

NATIONAL QUALITY FORUM

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RENAL MEASURES STANDING COMMITTEE

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TUESDAY
JUNE 28, 2016

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The Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 9:00 a.m., Constance Anderson and Peter Crooks, Co-Chairs, presiding.

PRESENT:

CONSTANCE ANDERSON, BSN, MBA, Co-Chair; Vice President of Clinical Operations, Northwest Kidney Centers

PETER CROOKS, MD, Co-Chair; Senior Consultant - Renal Business Group, Kaiser Permanente

ISHIR BHAN, MD, MPH, Director of Nephrology Informatics, Partners Healthcare, Massachusetts General Hospital

LORIEN DALRYMPLE, DNP, Nurse Practitioner, American Nurses Association

ELIZABETH EVANS, DNP, Nurse Practitioner, American Nurses Association

MICHAEL FISCHER, MD, MSPH, Staff Physician, Associate Professor of Medicine, Department of Veterans Affairs

STUART GREENSTEIN, MD, Professor of Surgery, Montefiore Medical Center

DEBRA HAIN, PhD, APRN, ANP-BC, GNP-BC, FAANP, Associate Professor, Adult Nurse Practitioner, Doctor of Philosophy, Doctor of Nursing Science, American Nephrology Nurses' Association

LORI HARTWELL, President/Founder, Renal Support Network*

FREDERICK KASKEL, MD, PhD, Chief of Pediatric Nephrology, Vice Chair of Pediatrics, Children's Hospital at Montefiore Medical Center

MYRA KLEINPETER, MD, MPH, Associate Professor of Clinical Medicine, Tulane University School of Medicine

ALAN KLIGER, MD, Clinical Professor of Medicine, Yale University School of Medicine; Senior Vice President of Medical Affairs, Chief Quality Officer, Yale New Haven Health System

LISA LATTS, MD, MSPH, MBA, FACP, Deputy Chief Health Officer, Watson Health, International Business Machines Corporation

KARILYNNE LENNING, MHA, LBSW, Senior Quality Improvement Facilitator, Telligen

FRANKLIN MADDUX, MD, FACP, Executive Vice President for Clinical and Scientific Affairs, Chief Medical Officer, Fresenius Medical Care North America

ANDREW NARVA, MD, FACP, FASN, Director, National Kidney Disease Education Program, National Institute of Diabetes and Digestive Kidney Diseases - National Institute of Health

JESSIE PAVLINAC, MS, RD, CSR, LD, Director, Clinical Nutrition, Food & Nutrition Services, Oregon Health & Science University

MICHAEL SOMERS, MD, Associate Professor in Pediatrics/Director, Renal Dialysis Unit; Associate Chief, Division of Nephrology, American Society of Pediatric Nephrology/Harvard Medical School/Boston Children's Hospital

JOHN WAGNER, MD, MBA, Director of Service, Associate Medical Director, Kings County Hospital Center

JOSHUA ZARITSKY, MD, PhD, Chief of Pediatric Nephrology, Nemours/A.I. duPont Hospital for Children

NQF STAFF:

ANN HAMMERSMITH, JD, General Counsel
POONAM BAL, Project Manager
ANDREW LYZENGA, Senior Director
YETUNDE ALEXANDRA OGUNGBEMI, Project Analyst
SARAH SAMPSEL, Senior Director
KATHRYN STREETER, Senior Project Manager

ALSO PRESENT:

JOEL ANDRESS, PhD, Centers for Medicare and
Medicaid Services
JENNIFER BRAGG-GRESHAM, PhD, University of
Michigan School of Public Health*
CLAUDIA DAHLERUS, PhD, University of Michigan
Kidney Epidemiology and Cost Center
RONALD HAYS, PhD, Fielding School of Public
Health, University of California, Los
Angeles*
SEHEE KIM, PhD, University of Michigan Kidney
Epidemiology and Cost Center
JOE MESSANA, MD, University of Michigan
Hospitals and Health Centers
LISA MCGONIGAL, MD, MPH, Kidney Care Quality
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ROBYN NISHIMI, PhD, Kidney Care Quality
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DOUG SCHAUBEL, PhD, University of Michigan
Kidney Epidemiology and Cost Center
JON SEGAL, MD, University of Michigan Kidney
Epidemiology and Cost Center
JACK WHEELER, PhD, University of Michigan Kidney
Epidemiology and Cost Center
ELIZABETH WITTEN, Witten and Associates

* Present by teleconference

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1 P-R-O-C-E-E-D-I-N-G-S

2 9:04 a.m.

3 MS. STREETER: Hello. Good morning,
4 everyone. I think we'll go ahead and get
5 started. I'm Katie Streeter, senior project
6 manager here with the Renal Team at NQF and we
7 just wanted to go over a few logistics before we
8 proceed with the meeting.

9 As a reminder, this call, as all of
10 our calls, is open to the public. So please
11 remember to mute your line if you're on the
12 phone. It just really helps with the noise.

13 All of our materials are available on
14 the committee SharePoint page. If you're having
15 any difficulty accessing the documents please
16 email Poonam or myself, and we can help you with
17 resetting your password or whatever else may be
18 needed.

19 Also, just as a reminder, if you wish
20 to speak at any time during your meeting, you can
21 put your name tag up like this, and we will be
22 sure to call on you.

1 Also, the speakers all have an on and
2 off button. Only three microphones can be on at
3 one time. So if you're not speaking please be
4 sure that the microphone is off.

5 I would like to turn this over to Ann
6 Hammersmith, our general counsel, so she can
7 begin with roll call and discussing disclosures
8 of interest.

9 MS. HAMMERSMITH: Thanks, Katie. I'm
10 Ann Hammersmith. I'm NQF's general counsel.
11 Those of you who have served on this committee or
12 another committee at NQF are familiar with the
13 oral disclosures. I'll go over the instructions
14 quickly, and then we'll go around the table.

15 You received a rather lengthy form
16 from us when you applied to sit on the committee.
17 We asked you detailed questions about your
18 professional activities.

19 Now we are going to ask you to go
20 around the table and disclose what you believe is
21 relevant to your service on the committee, only
22 if relevant to the service on the committee.

1 So we're particularly interested in
2 your disclosure of relevant consulting, speaking,
3 research grants. Don't have to disclose every
4 grant you've ever gotten, only if it's relevant
5 to the subject matter before the committee.

6 Just because you disclose does not
7 mean you have a conflict. You may have served on
8 a committee for a professional society or
9 something like that. That is not necessarily a
10 conflict.

11 So with that, let's go around the
12 table. Tell us who you are, who you're with and
13 if you have anything to disclose. We'll start
14 with the co-chairs.

15 CO-CHAIR CROOKS: Let's try that one.
16 Good morning, everyone. I'm Peter Crooks, and
17 it's my fourth time, I think, I've had the
18 pleasure to co-chair this meeting, and I'll just
19 say welcome to everybody, and thank you for
20 coming.

21 I would disclose that I was a quality
22 developer as -- a developer for the measure last

1 year. I'm getting into the time zone here.

2 Excuse me for a second as I move from West Coast
3 to East Coast time.

4 I was a developer on the optimal ESRD
5 starts measure that was approved last time, which
6 is conceivably related to the vascular access
7 measures that are on the docket today.

8 In talking it over with the staff and
9 thinking it through, I don't think it's truly
10 related. It's a different population.

11 But if anybody on the committee has
12 concerns about, it you can speak now or soon, and
13 I can recuse myself from those measures
14 discussions if needed. Otherwise, I can think of
15 no other disclosures. Connie?

16 CO-CHAIR ANDERSON: Good morning. I'm
17 Connie Anderson from the Northwest Kidney Centers
18 in Seattle. I was a member of the NCQA or NRAA
19 Quality Committee. But there is no conflict of
20 interest there.

21 I was part of the KCC Quality Group,
22 KCP Quality Group but it's been two years. So I

1 have nothing to disclose.

2 MEMBER KASKEL: I'm Rick Kaskel, a
3 pediatric nephrologist from Albert Einstein
4 College of Medicine at Montefiore Medical Center.
5 I think it's the third time I'm sitting on the
6 committee. I don't have any conflicts of
7 interest, and I work with ASPN, American Society
8 of Pediatric Nephrology.

9 MEMBER GREENSTEIN: I'm Stu
10 Greenstein, a transplant surgeon at Montefiore
11 Medical Center. I guess I'm the only surgeon
12 here so I'll try to be quiet most of the times.

13 And I have no conflicts. I also
14 represent the American Society of Transplant
15 Surgeons.

16 MEMBER MADDUX: Hi, I'm Frank Maddux.
17 I am chief medical officer and nephrologist of
18 Fresenius Medical Care North America. I am also
19 the chair of Kidney Care Partners, which is a
20 sponsor for the Kidney Care Quality Alliance.

21 I have not been involved in the
22 measure development that we're going to have

1 under discussion at 3:30 p.m. on medication
2 reconciliation.

3 But I have had prior extensive
4 discussions with CMS and others from a technical
5 expert standpoint on the Measures 2977 and 2978
6 related to vascular access in catheters. Those
7 would be my disclosures.

8 MEMBER SOMERS: I'm Michael Somers.
9 I'm a pediatric nephrologist from Boston
10 Children's Hospital. I don't have any
11 disclosures.

12 MEMBER DALRYMPLE: My name is Lorien
13 Dalrymple. I'm a nephrologist at U.C. Davis.
14 With respect to the measures today, I did serve
15 on the CMS Technical Expert Panel for Comorbidity
16 Adjustment for the SHR and SMR.

17 I did participate in the face validity
18 testing of the medication reconciliation measure
19 that we'll be discussing later today. I do
20 receive research support from a number of
21 organizations.

22 But they include Dialysis Clinic

1 Incorporated, which is a dialysis organization
2 and AHRQ for quality indicators. But those are
3 related to PSIs and IQIs.

4 I don't know if we will be discussing
5 the metrics submitted by Peter last year, but my
6 husband is a physician partner at Kaiser and has
7 shares in TPMG.

8 And last, I'm currently employed by
9 U.C. Davis but effective September of this year
10 will be with Fresenius.

11 MEMBER BAHN: I'm Ishir Bhan. I'm a
12 adult nephrologist at Mass General Hospital, and
13 I have no disclosures.

14 MEMBER FISCHER: I'm Michael Fischer.
15 I'm an adult nephrologist at the Jesse Brown and
16 Hines VA in Chicago. I am a member of the VA
17 Dialysis Steering Committee where we work on
18 developing our own internal performance measures.

19 I'm also a member of the RPA Quality
20 Safety and Accountability Committee.

21 MEMBER LENNING: Good morning. I'm
22 Karilynn Lenning, and I work for a company

1 called Telligen, currently contracted with the
2 state of Iowa to work on the state innovation
3 model, and I have no disclosures.

4 MEMBER NARVA: I'm Andy Narva. I'm a
5 nephrologist at NIDDK. I direct the National
6 Kidney Disease Education Program, and I have no
7 conflicts. Only existential ones.

8 MEMBER WAGNER: Good morning. I'm
9 John Wagner. I'm a nephrologist in Brooklyn, New
10 York. I am the associate medical director of New
11 York City Health and Hospitals, Kings County, and
12 the President of the National Forum of ESRD
13 Networks.

14 I'm a director emeritus of IPRO, which
15 is a quality improvement network, and my forum
16 has a membership on the KCQA, although I haven't
17 participated directly in those activities, and
18 I've served on a prior TEP panel that had to do
19 with quality metrics in ESCOS. But I don't
20 believe I have any conflicts for today.

21 MEMBER HAIN: Hi, I'm Debbie Hain.
22 I'm an associate professor at College of Nursing

1 at Florida Atlantic University in Boca Raton and
2 I am also a nurse practitioner in the Department
3 of Nephrology at Cleveland Clinic, Florida. I
4 don't have any disclosures related to the
5 measures today.

6 MEMBER EVANS: I'm Beth Evans. I'm a
7 nephrology nurse practitioner in Albuquerque, New
8 Mexico working with a private practice. I'm
9 representing the American Nephrology Nurses
10 Association, and I have no disclosures.

11 MEMBER PAVLINAC: Good morning.
12 Jessie Pavlinac, Director of Clinical Nutrition
13 at Oregon Health and Science University in
14 Portland and a transplant dietician.

15 I serve on the Network 16 Board of
16 Directors and the Medical Review Board is the
17 only thing I can think of. We're interested in
18 quality indicators, of course.

19 MEMBER KLEINPETER: Hi, I'm Myra
20 Kleinpeter, adult nephrologist, Tulane
21 University. I've served on the previous version
22 of this committee, also on the committee looking

1 at ESCOs, and on the Medical Review Board for
2 Network 13, and I have no conflicts of interest
3 at this time.

4 MEMBER LATTIS: Hi. I'm Lisa Latts.
5 I'm an internist. As of last week, I'm the
6 Deputy Chief Health Officer with IBM Watson
7 Health, and I have no conflicts.

8 MEMBER KLIGER: Hi. Alan Kliger. I'm
9 a nephrologist in New Haven, Connecticut,
10 employed by the Yale New Haven Health system as
11 their chief quality officer, and I was nominated
12 to this committee by the Renal Physicians
13 Associations, and I have no disclosures.

14 MS. HAMMERSMITH: Okay. I believe we
15 have a committee member on the phone, Lori
16 Hartwell. Is Lori Hartwell on the phone?

17 MEMBER HARTWELL: Yes. Good morning,
18 everyone. My name is Lori Hartwell, and I'm the
19 president and founder of Renal Support Network,
20 and I've been a patient since 1968.

21 I'm a board member of Kidney Care
22 Partners, but I have no disclosures.

1 MS. HAMMERSMITH: Okay. Thank you.

2 Is there anyone else on the phone, any other
3 committee members?

4 Okay. Just a few reminders before I
5 leave you today. You are all experts, and that's
6 why you're serving on the committee. You don't
7 represent your employer. You don't represent
8 anyone who's nominated you for service. You
9 don't represent a professional society to which
10 you belong. You are subject matter experts, and
11 you sit as individuals.

12 The other reminder is that to make a
13 conflict of interest process work we count on all
14 of you as committee members. So if during the
15 meeting you think that you have a conflict, if
16 you think somebody else has a conflict, or you
17 think that someone is behaving in an unduly
18 biased manner, we ask you to speak up in real
19 time. You're always welcome to bring it up in
20 the meeting.

21 If you'd rather not do that you can go
22 to your co-chairs who will go to NQF staff, or

1 you can go directly to NQF staff. Any questions
2 or comments? Questions for each other or
3 questions for me?

4 Okay. Thank you.

5 MS. STREETER: Thank you. At this
6 time, I'd also like to have the opportunity for
7 my team members to introduce themselves. Poonam?

8 MS. BAL: So I'm Poonam Bal, the
9 project manager on this project. I look forward
10 to working with you guys again.

11 MR. LYZENGA: Hi, Andrew Lyzenga,
12 senior director on the project, my first time
13 working with this topic area and with this
14 committee. So look forward to working with you
15 all as well.

16 MS. SAMPSEL: I'm Sarah Sampsel,
17 basically considered, I guess, a consulting
18 senior director. Since I worked with you all
19 last time, I'm now full time with NQF, and so I'm
20 just supporting Andrew in the transition as he
21 takes over this work.

22 MS. OGUNGBEMI: Good morning. I'm

1 Alexandra Ogungbemi, and I'm the project analyst
2 on the Renal Standing Committee.

3 MS. STREETER: I'd also like to point
4 out that we have Elisa Munthali and Marcia Wilson
5 here with us from NQF. Oh, we have -- Mike's
6 coming. Oh.

7 But thank you for being here with us
8 today as well, and thank you all for being here
9 with us today. This is our second in-person
10 meeting as a standing committee.

11 Just a refresher, some ground rules
12 for today's meeting. During the discussions all
13 committee members, co-chairs, developers and
14 staff are responsible for ensuring that the work
15 of the meeting is completed during the time
16 allotted.

17 During these discussions, committee
18 members should be prepared, having reviewed the
19 measures beforehand. We did receive your
20 comments through the worksheets on SharePoint,
21 and we have incorporated them into each measure
22 worksheet.

1 We ask that you base evaluation and
2 recommendations on the measure evaluation
3 criteria and guidance. Please remain engaged in
4 the discussion without distractions. Keep
5 comments concise and focused. Avoid dominating a
6 discussion and allow others to contribute, and
7 indicate agreement without repeating what has
8 already been said.

9 Process for measure discussions, we
10 are very fortunate to have the measure developers
11 present at our meeting. We do have a place
12 designated at our main table for the introduction
13 and discussion of their measures so that they may
14 more easily respond to questions from our
15 committee and correct any misunderstandings about
16 their measures during our discussion.

17 As with the case with the committee
18 members, developers may put up their cards to
19 indicate when they wish to respond to questions
20 raised or correct any statements about their
21 measures.

22 So voting on endorsement criteria,

1 just a quick refresher. We do have four main
2 criteria that we will be using as a basis to
3 evaluate the measures. The criteria are specific
4 in the -- the criteria are in the specific order
5 in that there is a hierarchy. The first two are
6 must-pass criteria: importance to measure and
7 report, and scientific acceptability of the
8 measure properties. We then move on to
9 feasibility and usability and use.

10 We do have a new maintenance process
11 that has been implemented since we last met, and
12 when we get to our first maintenance measure for
13 review we will walk you through that new process.

14 So voting during today's meeting, you
15 should all have a clicker. If you do not, please
16 let us know. As like last time, you will aim
17 your clicker towards Yutende here and -- are we
18 doing a test or no? We can do a test just to
19 make sure everyone's clicker is working. We do
20 have one remote participant, Lori, and she will
21 be voting through our online web platform.

22 So related and competing measures, we

1 have identified some related and competing
2 measures. The way we structured our agenda is
3 that after we review each measure, if there
4 happens to be relating and competing measures, we
5 will have that discussion afterwards.

6 Developers were asked to consider how
7 they can work together or otherwise align
8 measures, and the committee will be invited to
9 ask developers about harmonization opportunities
10 when each measure is being discussed.

11 And if we -- are there any questions
12 about the process for today's meeting? And if
13 not, we can jump right in to our first measure.
14 Actually, we'll start with our test, yes, test
15 for voting.

16 MS. BAL: So we're just going to do a
17 quick test to make sure that everybody's clicker
18 is working. As you remember, if you see the
19 number that means it went through. If you do not
20 see the number, there's an error, and it did not
21 go through. Give us one second to get it up.

22 You can change your decision as long

1 as the screen is up. Also try not to change it
2 at the end once we've started the announcement.

3 Okay. So we have it up. All right.
4 So if everyone could just select something, and
5 then Lori, on the phone, if you could just reply
6 to my chat with any number just so we can make
7 sure we're getting it. All right. So I'm seeing
8 17.

9 If everyone can just click it again,
10 and please look at your screen to make sure the
11 number is showing up. And Lori, I did get your
12 messages.

13 MEMBER HARTWELL: Thank you. I'm
14 going to put you on mute, so I might take a
15 minute to answer, or a second.

16 MS. BAL: We're missing one person.
17 I'm just going to recount the people to make sure
18 that I'm on the right number. Hold on a second.

19 Okay. So it's slow. But I think
20 everyone's clicker is working, and we can move
21 forward with our first measure then, and I'll
22 give it to the co-chairs. Oh, I'm sorry.

1 Andrew.

2 MR. LYZENGA: I think we had one --
3 just we had one slide to just run -- quickly run
4 over the portfolio. I won't spend much time on
5 that either, just to remind you of some of the
6 general topic areas we're looking at here and
7 that we have in the portfolio.

8 I think most of this group is probably
9 pretty familiar with the measures in the
10 portfolio at this point. A few measures around
11 dialysis monitoring, monitoring for various
12 markers to try to avoid complications and
13 identify them, some measures related to dosing
14 and dosing adequacy, a bit of -- some measures
15 related to hemodialysis, vascular access. We'll
16 have some discussion around that, and then some
17 general measures related to ESRD management.

18 There is a sheet in your materials
19 that were printed out for you at your desk where
20 you can look through the full set of measures in
21 the portfolio, and I would encourage you to take
22 a look at that maybe during one of our breaks or

1 just during the day. So we will try to have a
2 brief conversation at the end of the day.

3 If we have some time around gaps, if
4 you have suggestions or ideas on gap areas in
5 this portfolio, areas where you think there needs
6 to be some more measure develop on the renal
7 topic area, we would welcome your input on that.

8 But I think we can kind of skip over
9 this and just get into the meat of our meeting in
10 the interest of time at this point and go to our
11 first measure, which I think is going to be our
12 measure related to the KDQOL survey.

13 Beth, did you want to comment?

14 CO-CHAIR CROOKS: We just came to 45
15 minutes. That's --

16 CO-CHAIR ANDERSON: We're way ahead of
17 schedule.

18 MS. WITTEN: Press speak. What a
19 unique way.

20 My name is Beth Witten. I'll just try
21 to -- I'm going to be reading my intro. Because
22 this is such an important measure, I want to make

1 sure that I say what needs to get said.

2 The current conditions -- well, first
3 of all, the measure is 0260, and it's an
4 assessment of health-related quality of life in
5 eligible patients, to be assessed once a year,
6 and that's not the exact wording of it.

7 But the current conditions for
8 coverage require clinics to offer eligible
9 patients a functional status survey at least
10 annually. This is an absolutely essential
11 measure because it is the only one that asks
12 patients how they feel about their lives on
13 dialysis physically, mentally, symptoms, burdens
14 and effects of kidney disease on their daily
15 life.

16 The current NQF-endorsed process
17 measure collects the percent of eligible patients
18 who complete the KDQOL-36, the 36-item survey,
19 with our without help at least once a year.

20 The scope of this review is whether
21 this process measure, not the survey, is
22 reliable, valid, feasible and usable. We kept

1 the exclusion for language.

2 The ESRD interpretive guidance
3 recommends using a translation or interpreter
4 like the language line, and, by the way, the RAND
5 site has 25 translations on it that can be used
6 to translate either the survey itself of 36, or
7 there's a chart that allows you to choose which
8 questions to ask.

9 If clinics exclude patients who speak
10 or read certain languages how will they provide
11 the mandated education and informed consent? Are
12 there differences in language exclusions or
13 patients' completions based on social work
14 caseload? We don't know that. That's something
15 that would be interesting to investigate.

16 We did change some other exclusions to
17 address misunderstanding and conform to the CFC.
18 We changed "less than three months at the
19 facility" to "less than three months on dialysis"
20 so the facility could consider baseline survey
21 results in the first reassessment in plan of care
22 required by the CFC during the fourth month of

1 dialysis.

2 We expanded the exclusion for
3 cognitive impairment, dementia or psychosis to
4 "unable to complete due to mental status" but
5 would be willing to revise this to "unable to
6 complete due to mental status that would
7 invalidate the results".

8 This would avoid staff excluding
9 patients with depression, anxiety or other mental
10 health diagnoses that would not invalidate the
11 results.

12 We removed "refused" from the
13 exclusion criteria so these patients will not be
14 removed from the measure denominator. We wanted
15 to allow patients the right to refuse, which is
16 their right, while also assuring that facilities
17 track individual patient refusals for plan of
18 care and aggregate data for quality assessment
19 and performance improvement.

20 Removing refusals as ineligible from
21 the denominator would result in a completion rate
22 at or near 100 percent. Response rates from one

1 large dialysis organization and KDQOL Complete,
2 which is the subscription service, were greater
3 than 80 percent and improving somewhat.

4 Different completion rates may reflect
5 how relevance and use of the survey are described
6 to patients. Please note that the scope of this
7 process measure was not to show whether the
8 KDQOL-36 is reliable or valid. This has been
9 documented in the U.S. and other countries,
10 ethnicities and languages.

11 The scope was not to assess whether
12 the scores are meaningful to outcomes, though we
13 did discuss this on Page 37 and that's at 2b.2.3.

14 And the scope was not to assess
15 whether interventions can change scores, although
16 multiple randomized control trials and posters at
17 national meetings have shown that they can.

18 We are seeking continued endorsement
19 of the current measure of percent of eligible
20 patients completing the survey with the goal of
21 bringing to NQF within a year an outcome measure.

22 And assuming that they're on the

1 phone, because they didn't expect to get on the
2 phone until a little bit later, I'll let Jennifer
3 Bragg-Gresham answer questions about her analysis
4 of the data, and Ron Hays answer questions
5 related to the reliability and validity of the
6 KDQOL-36 survey itself, because he was one of the
7 developers.

8 MR. LYZENGA: Just a quick note. As
9 we mentioned on our Q and A call, under our new
10 maintenance process, we have the ability to skip
11 over certain sections of evidence and scientific
12 acceptability if the committee feels that's
13 appropriate.

14 I think we, at the staff level, are
15 thinking that this measure has changed fairly
16 substantially. It's gotten new testing, new
17 evidence as a process measure since its last
18 review. So our recommendation is that we review
19 each of the criteria on this measure instead of
20 skipping over them if the committee thinks that's
21 appropriate.

22 CO-CHAIR CROOKS: So we're going to --

1 so when the other speakers come on, are we going
2 to stop and let them --

3 MS. WITTEN: Well, that was one of the
4 questions I probably should have asked you guys.
5 Because I don't know how you run your meeting. I
6 didn't know whether you had discussion based on
7 your comments that were made, or whether our
8 folks needed to discuss --

9 CO-CHAIR CROOKS: Were they going to
10 present different material or were they --

11 MS. WITTEN: They were going to -- no,
12 they were going to answer questions.

13 CO-CHAIR CROOKS: Yes. So maybe by
14 the time they come on we'll be able to ask them
15 any needed questions.

16 DR. HAYS: Yes. I'm on. Ron Hays.
17 But you probably want Jennifer more than me for
18 this. But I'm available for questions.

19 MR. LYZENGA: I think at this point we
20 can hand it over to our lead discussants and just
21 have those folks available on the phone to answer
22 questions or make clarifications if necessary.

1 MS. WITTEN: And I think Lorien is
2 going to go ahead and take the lead on this, and
3 Bobby isn't here today, so Lori Hartwell and I
4 will add in our comments as Lorien presents the
5 information.

6 MEMBER DALRYMPLE: Okay. So we'll go
7 ahead and get started. As already mentioned,
8 this is NQF Measure Number 0260, Assessment of
9 Health-Related Quality of Life in Dialysis
10 Patients.

11 Just briefly to remind everyone, the
12 numerator statement is the number of eligible
13 individuals with end-stage renal disease on any
14 type of dialysis who complete a KDQOL-36 with our
15 without assistance once per calendar year.

16 The denominator statement is the
17 number of individuals with ESRD, again, on PD in-
18 center hemo or home hemo, treated by the dialysis
19 facility during the calendar year, minus those
20 patients who meet exclusion criteria.

21 The exclusion criteria have been
22 significantly revised since prior endorsement and

1 now include those who are less than 18 years old,
2 those who are unable to complete the survey due
3 to mental status that could invalidate the
4 results, those who are non-English speaking or
5 reading and no native language translation or
6 interpreter is available.

7 Those who have been on dialysis for
8 less than three months, and then it's noted those
9 who decline to complete one survey can then be
10 subsequently surveyed and counted during the
11 calendar year.

12 So I will attempt to follow the script
13 and first, we just note that this is technically
14 undergoing maintenance review, but as pointed
15 out, it's been significantly revised with a lot
16 of new data.

17 So we will walk through it as if it is
18 a new measure. It was most recently endorsed in
19 2007. This is a process measure. In terms of
20 the evidence presented, it primarily relates to
21 the KDOQI Clinical Practice Guideline, looking at
22 associational level of GFR with indices of

1 functioning and well-being, and in this
2 guideline, it is suggested to establish a
3 baseline and monitor for changes in functioning
4 and well-being over time and that this is
5 important to assess the effect of interventions
6 on functioning and well-being.

7 Connie, would you like to add anything
8 else, or Lori, who's on the phone, to the basic
9 premise of the evidence before we go into details
10 of rating?

11 MEMBER HARTWELL: I think you covered
12 it.

13 CO-CHAIR ANDERSON: I think my only
14 comment is -- sorry. My only comment is in terms
15 of the GFR less than 60, and I'm wondering, since
16 this is focused on PD home hemo and in-center
17 patients on dialysis, I question the GFR of less
18 than 60 just because that's -- you're looking at
19 then chronic kidney disease patients at stage 2,
20 3, 4. So I wonder if that's --

21 MS. WITTEN: Well, our measure just
22 addresses patients that are on dialysis. So

1 although the KDOQI said less than 60, people that
2 are on dialysis have a GFR of less than 60. But
3 we are just asking for this related to eligible
4 dialysis patients.

5 MEMBER DALRYMPLE: And one aspect that
6 at least I thought it would be helpful for the
7 committee to discuss at large is it always
8 becomes a little bit difficult, I think, when the
9 evidence relates to something that's not directly
10 the measure under discussion.

11 So the measure under discussion is,
12 did you complete the KDQOL? It is not a measure
13 of functioning or well-being or what your PCS or
14 MCS scores are.

15 So personally, when I try and go
16 through algorithm one and try and rate the
17 evidence, it depends on how you interpret the
18 evidence relative to the measure.

19 So I'm curious whether other committee
20 members -- for example, if you go down our boxes,
21 does this fall more as a distal process step, for
22 example? Because you rate the evidence very

1 differently if you argue this as a distal process
2 step: completeness yes/no of the KDQOL-36 on an
3 annual basis.

4 So I thought it would be helpful for
5 us to discuss that as a group before we try and
6 rate the evidence relative to algorithm one.

7 So yes, and this is where I'm always
8 grateful for the staff because they're going to
9 hopefully stop us if we're going through the
10 boxes first.

11 So if we start at box one, this is
12 technically a process of care. Although I
13 recognize that the HRQOL is a patient-reported
14 outcome, that's not how this measure is
15 specified. This is measured as a process: did
16 you complete it, yes or no?

17 So my answer to box one is no. So
18 then you have this kind of wordy question that
19 look at measures that assess performance on an
20 intermediate clinical outcome, process, or
21 structure. Is it based on a systematic review?
22 But down below there's these little caveats.

1 Answer no if any of the following: evidence is
2 about something other than what is measured;
3 empirical evidence submitted but not
4 systematically reviewed based on expert opinion.

5 But you get down to this last
6 asterisk: distal process step is not the specific
7 focus of the evidence, such as monitoring BP at
8 each visit when the evidence is about treatment
9 of hypertension or relationship to mortality.

10 So my perspective was that this
11 measure is more a distal process step. It's
12 completion yes/no of a survey, not what are the
13 results of your survey.

14 So I answered no on this box. So then
15 I went down to number seven, is empirical
16 evidence submitted but without systematic review?
17 And the answer to that is no because we did get
18 systematic review in grading of the evidence,
19 although it's a slightly different grading schema
20 than the ones we're used to.

21 It has a lot of Rs, and there was one
22 S and one C. So then we get to ten, are there or

1 could there be performance measures of related
2 health outcome or evidence-based intermediate
3 clinical outcome or process?

4 I would answer that yes because
5 technically speaking the results of the KDQOL
6 could be an outcome, I believe. So then no
7 exception, no exception, no exception, and I got
8 to rate as insufficient.

9 But I know on the NQF staff's
10 preliminary eval, I think they got to a rating of
11 moderate. So I thought this was an area worth us
12 parsing out as a committee because when I worked
13 through the algorithm I rated it as insufficient.

14 MS. WITTEN: By the way, right now
15 I've got both Ron Hays -- well, actually I've got
16 three people on the phone: Ron Hays; Jennifer
17 Bragg-Gresham, who ran the statistics for us; and
18 Kristi Klicko, who handles the KDQOL Complete,
19 knows about the subscription service that scores,
20 reports, analyzes the data for that particular
21 program.

22 MEMBER ZARITSKY: I'll start off by

1 arguing with number ten. I mean, I understand --
2 I could answer number ten as no because I think
3 the meaningful thing is here there -- if I look
4 at the example for yes, propose to measure
5 whether BP is assessed at each visit instead of
6 BP control, I mean, here there -- I could answer
7 that no and then make it over to rate as
8 insufficient evidence with exception.

9 MEMBER DALRYMPLE: And I believe we
10 always have the ability to do exception on
11 evidence, right? Regardless of which box we end
12 up on, the committee can make an exception, and
13 we move forward in evaluating the measure? Is
14 that correct?

15 MR. LYZENGA: Yes, and we would first
16 take a vote, and if it came out as insufficient,
17 then we could revisit the question and ask, do we
18 want to make an exception? And rate it
19 insufficient with exception, and then we would
20 move on to the subsequent criteria.

21 MS. SAMPSEL: And I would just add,
22 Lorien, this isn't a new struggle. I mean, we

1 deal with process measures, and typically where
2 we're seeing them are, was functional status
3 assessed for orthopedic issues? Or something
4 like that. We also see it with pain measures.
5 Just simply, did you assess for pain? And
6 certainly there was a lot of support that that's
7 very important. It's supported in guidelines, et
8 cetera, and that is -- just if you care about
9 consistency's sake that is -- they're going
10 through with the exception of evidence.

11 MS. WITTEN: I'm having a little bit
12 of question about the process measure and why you
13 believe that it's not a process measure. I'm not
14 -- I've not researched it that closely.

15 MEMBER DALRYMPLE: We did -- oh, just
16 to clarify, we do believe it's a process measure.

17 MS. WITTEN: Okay.

18 MEMBER DALRYMPLE: We're just
19 following the algorithm for evaluating evidence
20 as it relates to a process measure.

21 MS. WITTEN: Okay.

22 MEMBER DALRYMPLE: So everyone's in

1 agreement with what you submitted. This is a
2 process measure.

3 MS. WITTEN: Okay. Okay.

4 CO-CHAIR ANDERSON: Okay. Is there
5 any further discussion? Are we ready to vote?

6 Oh, I'm sorry. Alan?

7 MEMBER KLIGER: I just had an issue
8 unrelated to what you raised. In the definition
9 of denominator exclusions is included "mental
10 status that could invalidate the results", and I
11 can't imagine how you would define a mental
12 status that would specifically invalidate the
13 results.

14 MEMBER DALRYMPLE: And Alan, I think
15 there's actually a lot of the exclusions that
16 need to be discussed probably in more detail.
17 And whether we want to do that at the validity
18 phase or sooner, but there are a number of
19 denominator exclusions that I think the committee
20 is going to raise concerns about.

21 CO-CHAIR CROOKS: I'd like to ask the
22 developer, this is about importance, a little bit

1 off the evidence. But is this not a CMS
2 condition of coverage that this be measured
3 already?

4 MS. WITTEN: This is.

5 CO-CHAIR CROOKS: And if that's the
6 case, what does having a measure add to the mix?

7 MS. WITTEN: We just wanted to
8 maintain the measure. It was introduced -- the
9 history of this particular measure is that it was
10 introduced by Donna Mapes, who was part of DOPPS.

11 She and I worked on this in 2006-2007,
12 and NQF endorsed it in 2007. The regulations
13 were in process of being reviewed and revised in
14 all of that time, and NQF endorsed it. CMS
15 adopted it under the Phase III clinical
16 performance measures on April the 1st of 2008.

17 But it was too late at that point to
18 get that into the regulation that this particular
19 survey be used. So it is in the conditions for
20 coverage that a social worker is supposed to
21 assess the health-related quality of life at
22 least once annually, and so the DOPPS data just

1 recently that was published shows that 97 percent
2 of their sample facilities in the United States
3 are surveying patients once a year for this
4 particular measure, and there are 13 percent of
5 facilities that are assessing patients at least
6 every six months.

7 So it's in use, and I'm not sure if
8 that quite answers your question or not. But
9 we're just trying to maintain the endorsement in
10 the plan for using the data that we now have,
11 which we didn't have in 2007, to come up with an
12 outcome measure because I think that would be
13 more valuable than this particular measure.

14 But this particular measure, as you
15 said, Sarah, is very similar to assessing pain or
16 assessing depression. It's, did you assess
17 it/did you not assess it? I would love to see
18 this in the CROWNWeb data.

19 We've been talking with CMS CROWNWeb
20 people about that, trying to get this in there to
21 look at is it assessed or is it not.

22 It looks like from DOPPS that it is

1 being assessed, and I know from data from
2 Fresenius and DaVita and from DCI and various
3 dialysis providers this process measure, it is
4 being done.

5 So percent of eligible patients taking
6 the survey, I learned from Fresenius that about
7 85 percent of their patients are completing the
8 survey, and approximately that amount, 80, over
9 80 percent in the KDQOL Complete database are
10 completing it.

11 CO-CHAIR CROOKS: Okay. Thank you.

12 So we need --

13 MEMBER DALRYMPLE: This is Lori
14 Hartwell. I just have a comment. I am a strong
15 proponent of the KDQOL. My one question is is
16 that if they check the box if they did the survey
17 or not, I'm reading through the SF-36, and in my
18 opinion many of the questions don't really apply
19 to how dialysis units can really improve my care,
20 and so I think -- for instance if you go through
21 the KDQOL, like, one of the questions is have you
22 felt calm and peaceful?

1 And one of my struggles is, as a
2 patient, the clinic needs to ensure that my
3 treatment is the best possible so I don't -- I
4 can go out and improve my quality of life.

5 So the question that -- there are
6 several of them, but, do you have cramps, do you
7 have itchy skin, these all impact my quality of
8 life, but the dialysis unit can actually impact.

9 They can educate me about phosphorous,
10 fluid retention. My one thought is if it's just
11 a process measure, that's fine. But if there
12 were ever to be an outcome measure, I think the
13 questions need to be shrunk so the dialysis unit
14 can actually improve it because some quality of
15 life is up to the patient to improve, and we need
16 to take a little responsibility.

17 But if we do not have a good
18 treatment, and we do not feel good, we cannot
19 make a difference in our own quality of life.

20 MS. WITTEN: Can I address that?

21 CO-CHAIR CROOKS: Briefly. This is --

22 MS. WITTEN: Going on longer.

1 CO-CHAIR CROOKS: I guess her comment
2 relates to, again, the importance of it. If it's
3 not the right instrument, or it's not measuring
4 the right thing, why should we be endorsing it, I
5 guess.

6 MS. WITTEN: The KDQOL-36, separate
7 from the SF-36, the KDQOL-36 has the first 12
8 questions are from the SF-36, but then they have
9 specific kidney-related questions, which -- the
10 SF-36 is what's called a generic instrument, and
11 this is a disease-specific instrument.

12 So this gets at the burden of kidney
13 disease, the symptoms and problems that a lot of
14 kidney patients have, people that are on
15 dialysis, and also gets at the effects of kidney
16 disease on their daily life.

17 And I can tell you that I've gone
18 through this survey, and I have come up with --
19 and this is not part of the measure -- I have
20 come up with things that various members of the
21 interdisciplinary team could do to address each
22 of the questions. And Lori is right. It's

1 important to address the results.

2 CO-CHAIR ANDERSON: I have a question
3 for the developer as well. Back in 2007-8 when
4 the conditions for coverage came out, things have
5 changed dramatically over those years, and now we
6 have pain assessments twice a year.

7 We have ICAHPS twice a year. We have
8 depression screening twice a year, and now KDQOL
9 at 120 days and then annually or more frequently.
10 And I'm concerned, and maybe it's a better
11 discussion for performance gap, of the burden of
12 surveys on our patients at this point.

13 And in 2016, as we're halfway through
14 the year, we're seeing a real decline in response
15 rates, and so I'm just real concerned about the
16 burden of survey, and Lori, I don't know if you
17 want to make a comment on that but -- and maybe
18 we should hold it for performance gaps.

19 But we are measuring our patients so
20 frequently with so many things that are now
21 mandated that from a provider standpoint and from
22 a patient perspective, we're hearing it's an

1 overburden.

2 MEMBER HARTWELL: I'm all for
3 measuring as long as somebody is reacting to what
4 I remark. I mean, if I fill out a survey, I
5 expect the unit or whoever is conducting the
6 survey to address what I just said. And so
7 that's the one -- the only thing that I would
8 stress is where patients, I believe patients get
9 fatigued. They fill out the survey. Nothing
10 changes.

11 MS. WITTEN: And I agree that patients
12 do have a lot of surveys to fill out. This
13 particular survey, though, is a broader survey
14 than just assessing for depression, and I'm
15 thrilled that they're assessing for pain.

16 I wish it was more than twice a year.
17 I personally would like to see it, how's your
18 pain, at each treatment. But I understand that
19 filling out a survey, that would be difficult.

20 I do think that people need to do the
21 survey, get the scores and go back to the patient
22 as soon as possible with those scores and talk to

1 them about what could be done about it.

2 CO-CHAIR CROOKS: So in one sense, it
3 may not -- in terms of evaluating, it may not
4 matter actually what's on the survey. The case
5 that I think they're trying to make is the
6 process of doing the survey causes -- is linked
7 to good outcomes.

8 Is that what the committee
9 understands? In other words, if that was the
10 case, it may not matter per se what's on the
11 survey from the logic of -- no?

12 MEMBER DALRYMPLE: I'm not sure I
13 understand the question, Peter. I mean, I would
14 suggest we move forward with voting on evidence
15 because I feel like we're getting to other
16 domains of evaluation, and if we need to discuss
17 the evidence more in length, but the measure as
18 specified is whether you did or did not complete
19 the KDQOL, and so it is a process of care. It
20 is, I think, a reasonable assumption that for you
21 to intervene on someone's functioning and well-
22 being, you have to complete a survey which

1 measures that, and the very first step in that
2 process is, yes or no, did you attempt to
3 administer and complete it?

4 But I think we should vote on the
5 evidence as it relates to the measure and then
6 move to the other domains because I feel like the
7 discussion is getting to other areas where I
8 think there will be a lot of robust discussion.

9 CO-CHAIR CROOKS: Before we vote on
10 evidence. Okay. Then let's take --

11 MS. BAL: All right. So before we
12 start, I just wanted to make one clarification.
13 If you are in favor of doing insufficient with
14 exception, we do have to get 60 percent or more
15 insufficient.

16 So if we don't get over 60 percent,
17 and then let's say more than 40 percent low, that
18 does not move forward for insufficient.

19 We would not vote on insufficient with
20 exception then. Is that clear for everyone?
21 Okay. I just wanted to make sure. Okay. So
22 I'll give it to Alexandra to start the vote then.

1 MS. OGUNGBEMI: All right. We are now
2 voting on Measure 0260, Assessment of Health-
3 Related Quality of Life in Dialysis Patients. We
4 are voting on evidence. Voting is open.

5 MS. BAL: Lori, please enter your vote
6 through the chat.

7 MS. BAL: We are still missing --
8 never mind.

9 MS. OGUNGBEMI: Voting is closed. Our
10 results are 0 percent high, 26 percent moderate,
11 16 percent low, and 58 percent insufficient.

12 MS. BAL: So we actually do need to do
13 a revote though because we have 20 people with
14 Lori on the phone, not 19. So we'll have to do
15 another vote because that one vote could make a
16 big difference.

17 MS. OGUNGBEMI: All right. We are now
18 voting on evidence for Measure 0260. Please
19 vote.

20 MR. LYZENGA: So in that case, I think
21 we will take a second vote to --

22 MS. OGUNGBEMI: So our results are 0

1 percent high, 25 percent moderate, 15 percent low
2 and 60 percent insufficient. So we are going to
3 move on to vote for evidence with exception.

4 We are now voting on Measure 0260,
5 evidence with potential exception to empirical
6 evidence. The options are one, insufficient
7 evidence with exception, and number two is no
8 exception. Please vote.

9 MS. BAL: Lori, we are waiting for
10 your vote. Could you please send through the
11 chat? We received it. Thank you.

12 MS. OGUNGBEMI: The results are 70
13 percent insufficient evidence with exception and
14 30 percent no exception. So Measure 0260 passes
15 with insufficient evidence with exception.

16 MEMBER DALRYMPLE: Okay. So we will
17 move on with opportunity for improvement. On
18 page 19 of the measure initially forwarded to the
19 group, there is information provided by the
20 developer on differences in the performance
21 measure between facilities that participate in
22 KDQOL complete and have at least 10 patients.

1 I think we can just -- although we
2 have data from 2013, 2014 and 2015, these are
3 overall relatively similar looking to me. So we
4 can just discuss the 2015 data.

5 There were 1,261 facilities with a
6 median score of 91.8 percent. The interquartile
7 range was 78 to 100 percent. The tenth
8 percentile was 61.2 percent.

9 So I think you could argue there is
10 some opportunity for improvement, although I
11 believe the developer said something that was
12 quite interesting earlier in the presentation
13 that this is if you include those who refuse in
14 the denominator, and I believe she said that if
15 you do not it's closer to 100 percent.

16 I may have misunderstood. But I think
17 that will be important for us to think about as
18 we get to the specifications. But the measure as
19 specified, I would say, does have some room for
20 improvement if you look at the lower probably 10
21 percent facilities and maybe even the bottom 25
22 percent.

1 In terms of the disparities data
2 that's presented, it's relatively limited, and
3 you can see that it is also presented by year
4 2013, 2014 and 2015, and we have information on
5 the mean age, distribution of sex and race, and
6 whether you do or do not have diabetes, according
7 to whether you completed the survey, you refused
8 or you were excluded.

9 And I'm not sure that we need to
10 discuss that in detail. I think everyone had an
11 opportunity to review it, and it's relatively
12 limited with respect to other measures we
13 sometimes need to review disparities data on.
14 Also --

15 MS. WITTEN: I don't remember whether
16 I heard you say it also includes all the patients
17 in the database, not just the ones that completed
18 the survey.

19 MEMBER DALRYMPLE: Yes, I focused on
20 the ones for comparison's sake.

21 MS. WITTEN: Okay.

22 MEMBER DALRYMPLE: And Connie, did you

1 have other comments, or Lori?

2 CO-CHAIR ANDERSON: No. I think you
3 covered it well, Lorien.

4 MEMBER HARTWELL: I'm good. Thank
5 you.

6 MEMBER DALRYMPLE: Do we want to pull
7 to the committee's pre-evaluations to view in
8 real time? I think that's easier than perhaps
9 Connie, Lori or I reviewing those.

10 But these are the comments the
11 committee submitted prior to our meeting today,
12 if anyone would like to re-highlight the
13 important points they made in writing prior to
14 the meeting.

15 MS. WITTEN: And Jennifer Bragg-
16 Gresham is on the phone right now. Do you want
17 her to speak to anything?

18 CO-CHAIR ANDERSON: Anybody have any
19 questions or comments? Shall we move forward
20 with the vote if there's no questions or
21 comments?

22 MS. WITTEN: Can I just say one thing,

1 that the data that relates the completion to the
2 outcomes is that 2b.2.3.

3 MS. OGUNGBEMI: We are now voting on
4 Measure 0260, performance gap. Options are high,
5 moderate, low and insufficient. Voting is open.

6 Results are 0 percent high, 60 percent
7 moderate, 40 percent low and 0 percent
8 insufficient. Measure 0260 for performance gap
9 lands in the gray zone.

10 MEMBER DALRYMPLE: So we'll move on
11 then. Any other comments before we - we'll move
12 on to reliability and validity. And first we'll
13 start with the specifications in more detail.
14 I'm on Page 22. It's probably a later page in
15 our most recent packet. But just to review the
16 details, we'll start with the numerator if that's
17 helpful to every. I'll try and be brief.

18 It is the number of eligible and not
19 excluded individuals with end-stage renal disease
20 on dialysis who complete a KDQOL-36 with or
21 without assistance at least once per calendar
22 year.

1 In terms of the denominator, it is the
2 number of individuals with ESRD on peritoneal
3 dialysis, in-center hemodialysis or home hemo who
4 are treated by the facility during the calendar
5 year minus those who need exclusions.

6 I think the exclusions are worth
7 discussing in a little bit more detail and we do
8 have very specific exclusions listed by the
9 developer including age less than 18.

10 Those who are unable to complete due
11 to mental status and it states in the details
12 from the medical record what is specifically
13 meant by that. I do not know and I imagine it is
14 open to significant interpretation.

15 The third exclusion is non-English
16 speaking or reading and no language translation
17 or interpreter is available - RAND translations
18 for the KDQOL or interpreter resources. And then
19 the last exclusion, which I think also warrants
20 more discussion is less than three months on
21 dialysis, which is a revised exclusion. It
22 previously was less than three months on dialysis

1 at the facility.

2 So from my perspective when I was
3 reviewing this measure I think one thing that
4 would be important to talk about as a committee
5 is what we think is appropriate in terms of
6 putting those who refuse into the denominator.

7 So they used to be excluded. If you
8 refused you were not counted in the numerator or
9 denominator but you now go into the denominator.
10 In terms of other aspects of the metric as
11 specified that I think are open to interpretation
12 is unable to complete due to mental status, the
13 issue around no interpreter available.

14 We actually have some data presented
15 by the developers on that.

16 And then last, this less than three
17 months on dialysis I think was revised to align
18 with conditions for coverage.

19 But from my perspective then put a
20 patient in a facility who may be there a very
21 short period of time. So there's no longer a
22 requirement that you're in that facility, let's

1 say, for at least four weeks or some time frame
2 that is reasonable by which you would expect a
3 KDQOL to be completed by the staff.

4 So that opens up the possibility again
5 of a denominator that's inappropriately
6 attributing patients to that facility and how
7 that would be handled is unclear to me.

8 But I think Connie and Lori, if you
9 want to add supplemental though and then other
10 committee members. I think there were a number
11 of thoughts around these specifications.

12 MS. WITTEN: Lori, do you want to have
13 any comments?

14 MEMBER HARTWELL: I just wanted to
15 just understand the rationale of not doing the
16 quality of life measure in the first 90 days. Is
17 it just because there's too much change in their
18 life and they need to adjust? That was my only
19 question I asked of the developer.

20 MS. WITTEN: Yes, that was - that was
21 the consensus when we introduced the measure
22 initially was that the patient was in a lot of

1 turmoil.

2 Also, another reason for aligning it
3 with the conditions for coverage is that if you
4 did the survey, say, within the first few weeks,
5 say, if you did it during the second month, the
6 first plan of care for the reassessment you want
7 it to align with that so that you get the results
8 in time to discuss it during the plan of care and
9 facilities have a plan of care meeting 15 days
10 after the first reassessment, which is supposed
11 to be done during the fourth month of dialysis.

12 So it was to try to get the data as
13 close to the plan of care meeting as possible.
14 If you're discussing data that's two months old a
15 lot of things may have changed.

16 CO-CHAIR ANDERSON: So one of my
17 comments is you're only doing the survey
18 annually. It's a point in time. It's at the
19 plan of care and you're capturing data that is
20 supposed to move on to a plan of care.

21 But again, things change during the
22 course of the year. So what survey tool do you

1 use if somebody has a catastrophic event and you
2 want to measure symptoms, let's say.

3 I'm not sure that this is really
4 capturing what it's trying to capture in terms of
5 identifying burden of disease, mental capacity
6 and signs and symptoms if you're only doing it
7 once a year and -

8 MS. WITTEN: The regulations say that
9 it needs to be done annually or as needed and you
10 talk about burden of doing a survey.

11 But if I were doing it I would - I'm
12 a renal social worker by background, by the way.
13 If I were doing it, I would do the survey. I
14 would do an intervention.

15 I would do a survey to see whether my
16 intervention made a difference, because over a
17 year period of time somebody could be
18 deteriorating and you could be doing all kinds of
19 things that don't get credited to you.

20 So we're trying to say at a minimum.
21 We're not trying to state a maximum. So people
22 can do it as often as they want to do it. I

1 believe, Ron, you're on the phone and I think in
2 the FAQs on the RAND site it says that, you know,
3 even monthly. But you talk about having to weigh
4 the burden.

5 CO-CHAIR ANDERSON: Well, and I think
6 the committee needs to consider the fact of the
7 burden of all these surveys.

8 If somebody is depressed I would do a
9 depression screening before I would do a KDQOL
10 again, or if somebody's complaining of the signs
11 and symptoms that you get on KDQOL then do you do
12 a pain assessment because it's chronic pain.

13 So I think we have so many tools and
14 so many measures here that compete with each
15 other in some ways.

16 So I think it's imperative that the
17 committee really think about what are we trying
18 to get out with the KDQOL. And yes, it's
19 annually or as needed, but are some other tools
20 that are out there that are now being regulated
21 and on the provider to perform -- are they better
22 tools than the KDQOL or is - you know.

1 MS. WITTEN: Well, the KDQOL symptoms
2 problems list is much more than just pain.

3 CO-CHAIR ANDERSON: Right.

4 MS. WITTEN: A lot of the symptoms -
5 itching -

6 CO-CHAIR ANDERSON: Congestive heart
7 failure, yeah.

8 MS. WITTEN: Yeah, pain - chest pain,
9 a variety of things that are important for
10 physicians and nurses, dieticians, even social
11 workers to know about.

12 So it's important, in my mind, to not
13 just throw out this survey and say let's just do
14 the pain and depression because that's going to
15 cover the -

16 CO-CHAIR ANDERSON: Yeah.

17 MS. WITTEN: - what we need to cover.
18 My personal belief is that only just covers a
19 small aspect of what's going on with dialysis,
20 and there are lots of things that can be done in
21 the way treatment is delivered, where treatment
22 is delivered, how treatment is delivered, that

1 will make a difference.

2 DR. HAYS: Yeah. So I think that the
3 point about burden is an important one about any
4 measure. You know, you don't measure it just be
5 measuring it.

6 You have to have a purpose and the
7 coordination across these different approaches is
8 critical. But I think it's probably beyond the
9 scope of this particular assessment.

10 I mean, this KDQOL is assessing a lot
11 of different things but the focus really is on
12 the kidney disease-targeted content that's
13 important to patients on dialysis and, you know,
14 it touches on pain and depressive symptoms but
15 that's not the point of the assessment.

16 CO-CHAIR CROOKS: Are there comments
17 on - other comments on specification? Are there
18 comments on specifications? Frank.

19 MEMBER MADDUX: Yeah. So I have one
20 question, Beth. Did you all analyze whether or
21 not if you move to refusals being included in the
22 denominator has there been any assessment of

1 whether that would simply increase the number of
2 mental status conclusions?

3 MS. WITTEN: Jen, you did the data
4 analysis.

5 DR. BRAGG-GRESHAM: Right. We did not
6 assess that and to us refusals, you know, were an
7 important piece that we felt should be in the
8 denominator because those are people who weren't
9 excluded so they really should have been eligible
10 to complete the survey. But that's something we
11 could look at.

12 CO-CHAIR CROOKS: Other questions,
13 comments?

14 CO-CHAIR ANDERSON: I would like to
15 ask the developer how you're defining mental
16 status.

17 MS. WITTEN: That was one of the
18 issues - oh, okay. Go for it.

19 MEMBER KLIGER: Yeah, I just want to
20 again raise questions about this exclusion which
21 seems remarkably confusing to me.

22 It says mental status - I'll start

1 with that. We don't have a routine way of
2 assessing and rating mental status. We, in the
3 record, have imprecise ways of assessing that.

4 But then particularly mental status
5 that could invalidate the results - we surely
6 never record mental status in the framework of
7 whether they can or cannot invalidate results.

8 In fact, the we clinicians don't know
9 anything about what does validate or does
10 invalidate results. So this definition seems to
11 me to be very troublesome.

12 MS. WITTEN: In the past, we had
13 dementia and cognitive impairment and active
14 psychosis. If that is an issue with this
15 particular part of the measure, you know, we
16 could fall back to that. That would not be
17 problematic.

18 Those all would invalidate the results
19 because if she's got somebody that's cognitively
20 impaired they're unlikely to even follow what
21 you're asking, depending on the level of
22 cognitive impairments.

1 And there's also tools that will
2 measure cognitive impairment. There's many
3 mental status exam that's not even very difficult
4 and primary care physicians do that all the time.

5 MEMBER KLIGER: Only that if you're
6 going to make that a criterion it means that that
7 needs to be then done and registered on every
8 patient in the dialysis unit.

9 MS. WITTEN: I think the social
10 workers in the dialysis clinic who have Master's
11 degrees in social work should be able to assess
12 their patients' mental status to determine
13 whether they are cognitively impaired
14 sufficiently that it would invalidate the
15 results.

16 I was concerned when we changed the
17 measure to be more - to be broader, that some
18 social workers who are overburdened by caseloads
19 and so forth would say well, my patient's
20 depressed - I'm not going to give this survey and
21 - or my patient is anxious.

22 Right now, we have some situations,

1 and this is anecdotal, where we have social
2 workers that call the technical expert at Medical
3 Education Institute and say, my patient is blind
4 - is that an exclusion.

5 Then we say no, you can sit down with
6 the patient. There's no reason why you can't
7 fill that survey out with a blind patient.

8 So there are - we aren't sure. We
9 can't know for sure that there are other reasons
10 why people are not getting this survey. I would
11 love to study it more to find out whether patient
12 caseloads affect the social workers offering the
13 survey.

14 I would like to know whether social
15 workers are using the tool that we have - that
16 Dori Schatell and I wrote that's an eight-page
17 document that explains to them how to offer the
18 survey, how to do the - how to tell the patient
19 it's relevant to them so that they are interested
20 in taking it.

21 It's, like, doctors don't like telling
22 patients your - you have kidney failure - you're

1 going to need dialysis. The social workers hate
2 to tell patients they have low scores.

3 My sense on what I tell social workers
4 is but isn't it good that you know that this is
5 going on right now because now you can do
6 something about it where the patient could die if
7 they did not know they had low scores and
8 continued to deteriorate with nothing from the -
9 from the clinic.

10 MEMBER DALRYMPLE: Frank, do you have
11 a comment?

12 MEMBER MADDUX: The only comment I
13 would have is I think with the utility of the
14 fiscal and mental component scores in a wide
15 variety of things other than pure outcomes for an
16 individual, predicting patients that have more
17 needs than others, the generalization to mental
18 status that might exclude depression, anxiety and
19 stress-related disorders I think would be an
20 unintended consequence that I would want to avoid
21 in the utility of this.

22 And even though I'm sensitive to the

1 burden, I think the KDQOL has been an incredibly
2 important tool in developing predictive analytics
3 on identifying subpopulations of patients with
4 special needs. And I'm a little bit concerned
5 that that exclusion is probably too general that
6 might lead to essentially patients not
7 participating.

8 MS. WITTEN: And so would it be -
9 since I don't know how this group operates.

10 CO-CHAIR CROOKS: Let me ask the staff
11 that question that you're thinking of. If the
12 committee is in agreement that this is a flawed
13 specification and it needs to be addressed can we
14 continue consideration with the caveat that they
15 come back to us with some language that makes it
16 much more specific?

17 MR. LYZENGA: I think we would have to
18 vote on the measure as specified right now and
19 ask the developer to come back during public
20 comment perhaps. You know, we could maybe revote
21 at that time.

22 CO-CHAIR CROOKS: So you're saying

1 that we should vote on it as it is and then -
2 okay. Okay. Other comments on specifications
3 before we go to reliability?

4 MEMBER WAGNER: I just had a question
5 regarding translation services. Do we have any
6 data to speak to how successful use of
7 translation services is with respect to a
8 completion of the survey?

9 MEMBER DALRYMPLE: Within the measure
10 we do have what is clearly high variability
11 between facilities than their use of
12 interpretation services and I think you can cross
13 some inferences based on that.

14 MS. WITTEN: And if you think about
15 it, there are states that have populations of
16 people that speak multiple different languages.
17 There are Spanish - there are 25 - as I said
18 earlier, 25 translations on the RAND site that
19 are available including American Spanish, Spain
20 Spanish.

21 The KDQOL complete has several
22 languages - Tagalog, Korean - you know, a variety

1 of different languages. Kristi Klicko from MEI
2 is on the phone also and could tell you more
3 about all the translations that are available
4 there.

5 One of the things that I'm concerned
6 about, and this is where I was talking about
7 earlier, is that there may be situations where a
8 social worker doesn't know what language the
9 patient speaks and doesn't know - they've called
10 in to the technical support at the MEI site and
11 have just said a patient is from X country and
12 don't know what the language is.

13 And so there may actually be a
14 translation available but they're so overworked
15 because, I mean, people that work in dialysis
16 clinics know the caseloads are high.

17 They may just say a language
18 exclusion. I wish I could guarantee that ever
19 social worker is as invested in this measure as I
20 am.

21 CO-CHAIR ANDERSON: John?

22 MEMBER WAGNER: Yeah. I guess I was

1 referring more specifically to the use of a human
2 translator to assist in the completion of the
3 survey.

4 Obviously, if there is a printed
5 translation that's helpful. But do we know
6 whether the use of facilitated translation and
7 coaching is important in certain populations and
8 does that - does that have an impact on the
9 completion of service.

10 MS. WITTEN: I don't think we know
11 whether the interpretation - who interprets the
12 survey to the patient makes a difference or not.
13 But language line and various - there are
14 certified interpreters that are medical
15 interpreters that the facilities could call upon
16 to do this.

17 The other thing is for large dialysis
18 organizations if they know that they have
19 patients that speak different languages could
20 probably get a translation of the survey for that
21 language.

22 CO-CHAIR ANDERSON: And from the

1 provider's side maybe I can provide you with some
2 help and information. We use a system called On
3 Demand.

4 Again, it has lots of different
5 languages on it but, again, the variability of
6 the translation is really high and I'll give you
7 an example.

8 We translated angel food cake with one
9 of our dieticians and it got translated to cake
10 of death.

11 So you never really know what they're
12 saying because you don't speak the languages and
13 so we know there's variability in using
14 interpretive services. If it's in a written
15 language you're much better off.

16 MS. WITTEN: But would it be better to
17 exclude those people and not give them -

18 CO-CHAIR ANDERSON: And not to say
19 they have the same problems as the rest so -

20 MS. WITTEN: Yeah. The one thing that
21 I think about is if you've got a language
22 difficulty how are you educating patients? How

1 are you getting informed consent with those
2 patients? You have to do that too.

3 So, you know, it seems reasonable that
4 you could use the same people that you're using
5 for that because you're relying on that for the
6 treatment itself as you do for the survey.

7 MEMBER FISCHER: I just have one
8 comment. So as I understand it, the other thing
9 that concerns me is that folks who refuse that's
10 no longer an exclusion and it seems like the
11 rationale was to incentivize facilities achieving
12 higher completion rates.

13 But there really isn't a lot of
14 specific guidance given to facilities as to how
15 to do that. It just kind of says make efforts to
16 increase the number of patients and I think
17 there's an art to that and that's a little bit
18 difficult.

19 You know, in retrospect one way to try
20 to incentivize that would have said, you know,
21 someone has to refuse twice or three times in a
22 certain time period.

1 This is how we've done it actually in
2 the VA with things like this where you try to
3 incentivize high completion rates but not given
4 broad brush punitive measures, again, to a
5 facility for a low completion rate when sometimes
6 there's a limited ability of a facility or a
7 specific provider to increase that, to increase
8 someone completing a survey.

9 That's how I understand the change.
10 I mean, that would be my concern.

11 MEMBER DALRYMPLE: And I think that's
12 an important point. I think patients have the
13 right to refuse completing surveys and if you
14 give kind of guidance, just make reattempts with
15 no limit.

16 So I like your example of you cap the
17 number of attempts so that patients really do
18 have the autonomy to not complete surveys they
19 wish not to complete.

20 I do think we should try and move on
21 to reliability unless other committee members -
22 Lisa?

1 MEMBER LATTS: Can I just make one
2 comment about the refusals? I do think that if
3 you do use that as an exclusion it is an
4 opportunity to game the system on the part of the
5 facility because they could say, oh, are you
6 refusing - yes, you're - you know, I mean, there
7 are ways to encourage people to do it and there
8 are ways to discourage people to do it.

9 And I think with the understanding
10 that the results shouldn't be 100 percent because
11 you are - you know, people are going to refuse.
12 If there is an abnormally large rate of refusals
13 that suggests something that should be looked at.

14 MEMBER MADDUX: I completely agree.
15 That's why a more nuanced approach is having a
16 set number - a higher number of refusals, not
17 just yes/no but the person had to refuse twice or
18 three times during a certain time period, which
19 we've tried to do.

20 Again, as Laurien touched upon,
21 keeping it patient centered, especially given the
22 number of surveys patients are being asked to

1 complete.

2 MEMBER DALRYMPLE: I was just looking
3 at the time. Should we move on to reliability
4 testing?

5 CO-CHAIR ANDERSON: Can we take a
6 vote, please?

7 MEMBER DALRYMPLE: Oh, we haven't gone
8 to discuss the reliability testing. So we will
9 go through this. The developers do provide
10 reliability testing for years 2013, 2014 and
11 2015. I am assuming that the data presented in
12 2015 is a typo.

13 So we will assume the reliability is
14 actually .926 to .93. So and that is looking at
15 between facility differences. There is
16 distribution of reliability also provided.

17 From my perspective, the one issue
18 that was not addressed for reliability is whether
19 it differs by facility size which you would
20 potentially expect it to because smaller
21 facilities have a smaller annual. I think the
22 committee should discuss that first and then if

1 we need developer feedback we will ask for it.

2 But did anyone have any comments on
3 the reliability testing or the distribution of
4 the reliability as presented? Should we move on
5 to discussing the validity?

6 Okay. So the validity testing - I
7 know there were a number of pre -

8 CO-CHAIR CROOKS: I think we -

9 CO-CHAIR ANDERSON: Sorry, Peter.
10 It's time for a vote.

11 CO-CHAIR CROOKS: So we vote on specs
12 and reliability together in one vote, and then we
13 go on to validity, correct?

14 MEMBER DALRYMPLE: May I ask a
15 question then of the developer? Do you have any
16 reliability and information with respect to
17 facility size? Do smaller facilities have lower
18 reliability as compared to large dialysis
19 facilities?

20 DR. BRAGG-GRESHAM: So I did not look
21 at that specifically but based on, you know, the
22 equation for reliability that would - you know,

1 that would be expected.

2 MS. OGUNGBEMI: If there are no other
3 comments from the committee we are going to go
4 ahead and vote on reliability for Measure 0260.
5 This includes precise specifications and testing.

6 The options are one, high; two,
7 moderate; three, low; and four, insufficient.
8 Voting is open.

9 MS. OGUNGBEMI: Results are for
10 Measure 0260 on reliability 15 percent high, 40
11 percent moderate, 45 percent low and 0 percent
12 insufficient. So Measure 0260 passes on
13 reliability.

14 CO-CHAIR CROOKS: I'd just like to
15 comment that I think this is the wrong process,
16 that if we're voting on specs alone it probably
17 wouldn't have passed.

18 But if you put specs and reliability
19 together then everybody's thinking oh, the
20 reliability looks good so they vote yes. And I
21 think this is a wrong result because of the way
22 we vote.

1 MS. OGUNGBEMI: So I need to make a
2 correction. It is - it falls in the gray zone.

3 CO-CHAIR CROOKS: It falls in the gray
4 zone? Okay.

5 MS. OGUNGBEMI: Yes.

6 CO-CHAIR CROOKS: But my comment still
7 stands. I think the specs could be terrible but
8 the reliability could be good. You know, it
9 doesn't -

10 MEMBER DALRYMPLE: Can I clarify with
11 the NQF staff? Doesn't validity testing also
12 incorporate considerations of the specifications
13 in some way because you can argue when you start
14 creating exclusions that maybe even on face
15 validity don't make sense then there can be a
16 validity failure as well.

17 I agree with you, we often vote on the
18 reliability testing in this section. But I think
19 validity is another opportunity to address this.

20 MR. LYZENGA: It is. The
21 specifications in the reliability section are
22 really intended to get at whether the

1 specifications are precise, understandable, can
2 be implemented consistently whereas, you know, as
3 you said, have another opportunity in validity to
4 talk about whether the specifications reflect the
5 evidence provided and truly reflect, you know, an
6 accurate view of quality as specified.

7 MEMBER FISCHER: Could I just ask a
8 question to the NQF staff? Could you, just for
9 my understanding, re-explain or redefine what
10 gray zone means? I don't recall entirely.

11 MR. LYZENGA: So this is something
12 that emerged out of some work that we had -- a
13 consensus task force. We wanted to acknowledge
14 places where there was not clear consensus across
15 the committee. When the measure does not receive
16 in excess for any particular criterion in excess
17 of 60 percent for below 40 percent, it falls in
18 the so-called gray zone.

19 In that case, the measure does move
20 forward to - for consideration against the
21 remaining criteria. But I believe we put it out
22 for comment and then we ask the public to give us

1 feedback on it and then take a revote, I believe,
2 after that to just sort of confirm or give
3 another go at the vote after we receive some
4 comment on that particular measure.

5 CO-CHAIR CROOKS: Revote would be by -
6 just so I'm clear, the revote would be by this
7 committee again.

8 MR. LYZENGA: The same committee, yes.

9 CO-CHAIR CROOKS: Okay. Thank you.

10 MR. LYZENGA: Considering, you know,
11 again, any public comment that comes in.

12 CO-CHAIR CROOKS: Okay. I just wanted
13 to make sure I understood the implications.
14 Thank you.

15 Okay. Let's move on to validity then.

16 MEMBER DALRYMPLE: Okay. So for
17 validity testing we actually have a fair amount
18 of data we can look at with respect to what the
19 developer provided with us.

20 First, we'll look at the linear mixed
21 model that is presented. My understanding is in
22 this model they looked at patient level quality

1 of life scores for each scale as the dependent
2 variable and the facility completion rate was the
3 main independent variable.

4 The models were adjusted for patient
5 level characteristics, age, sex, race and
6 diabetes. Facility clustering appears to have
7 been accounted for but I think we are missing
8 some information.

9 There's a blank in the description of
10 the methods. A compound co-variance structure
11 was used.

12 So we can look at the results of this.
13 The developers state they found a significant and
14 positive association between facility completion
15 rates and quality of life scores for these scales
16 and the MCS and PCS.

17 However, I did not find the
18 interpretation of the estimates to be intuitive.
19 So if other committee members were able to
20 interpret these estimates I think that would be
21 helpful.

22 If no one on the committee was

1 entirely clear how we should interpret the
2 estimates then I thought this would be helpful to
3 maybe just have the developers in one sentence
4 state for us how we should interpret the estimate
5 provided for, let's say, the MCS outcome or the
6 MCS estimate.

7 MS. WITTEN: Jen? Jennifer?

8 DR. BRAGG-GRESHAM: Sure. I'm happy
9 to go through. So interpreting facility level
10 co-variance is always a little tricky. So we
11 need to think about because the outcome was at
12 the patient level basically this estimate applies
13 to all the patients in the facility. So we set
14 up this first table to be the estimate of the
15 effect comparing, let's say, a facility that has
16 90 percent completion - or sorry, 80 percent to
17 one that has 90 percent.

18 So we're saying if the facility has a
19 10 percentage point higher completion rate then
20 you would expect all of the patients in that
21 facility to have, you know, the estimated
22 difference in their score. So in this case,

1 they're all positive.

2 So you'd say, you know, if you want to
3 look at the first one, symptoms - so in a
4 facility that has 90 percent completion rate
5 versus one that has 80 percent completion rate,
6 all of their patients on average had a .21 higher
7 symptoms score.

8 You know, so we know that's a small
9 effect. But I think it's important that it's
10 positive and it was significant in terms of, you
11 know, P value here. Does that help?

12 MEMBER DALRYMPLE: It does help. So
13 I just want to clarify. So for a 10 percent
14 higher completion rate, so comparing someone who
15 has a 90 percent versus 80 percent facility
16 completion rate, the average patient level
17 changed and the MCS would be .08. Is that
18 correct?

19 DR. BRAGG-GRESHAM: Correct. And it
20 wouldn't be changed. It would be - right.
21 Different. Right.

22 MEMBER DALRYMPLE: I'm sorry?

1 DR. BRAGG-GRESHAM: It would be a
2 different -

3 MEMBER DALRYMPLE: On average .08
4 higher?

5 DR. BRAGG-GRESHAM: Correct, yes.

6 MEMBER DALRYMPLE: Okay.

7 DR. BRAGG-GRESHAM: That is correct.

8 MEMBER DALRYMPLE: Okay. If the
9 committee members feel comfortable with that we
10 can move on to the other data presented. There
11 were data looking at the exclusion analyses.

12 The exclusion for age I'm sure none of
13 us who work in data are surprised that reported
14 age and calculated age sometimes don't match up.
15 So I think that's okay. It's real life.

16 If you then look at patient
17 characteristics by exclusion criteria you can see
18 we have information with respect to sex, race
19 and diabetes for each of the exclusions including
20 cognitive impairment or language barriers or in
21 the facility less than three months.

22 We then go on to have information

1 provided, looking at the odds of completed versus
2 refused or the odds of completed versus excluded
3 with respect to age, sex, race and I believe this
4 is year that the survey was completed. It's
5 reported as year per year.

6 But I notice there was a lot of pre-
7 committee comment and I had similar feelings that
8 it wasn't clear to me that this information was
9 helping me think about validity and potentially
10 even started to make an argument that there may
11 be a case mix issue or need for adjustment and I
12 saw others raise those concerns.

13 So although this was presented in the
14 validity testing with one purpose I think it's
15 probably more important that we as a committee
16 discuss what our inferences are when you look at
17 whether the odds of completing versus refusing or
18 perhaps completing versus exclusion are
19 different, depending on your age, sex, race and
20 the year.

21 So do committee members want to
22 discuss these? I know many people submitted

1 comments. So it may be helpful to just discuss
2 those more broadly. And Connie and Lori, if you
3 want to lead with that discussion.

4 CO-CHAIR ANDERSON: I think you've
5 stated it very well. Comments? Questions for
6 the developer? Conference question? All right.
7 Shall we vote?

8 CO-CHAIR CROOKS: I'd just like to
9 back up for a second, Lori, into the - and I may
10 have missed the - so the opportunity to discuss
11 this.

12 But I felt they were trying to make a
13 case that this is valid because units that do
14 more of these have - their quality of life scores
15 are higher actually as a - to prove validity and
16 that's questionable because patients who - you
17 know, units that have a lot of patients that
18 complete it may have healthier patients and more
19 mentis compos patients to do it.

20 So did you discuss that in your
21 analysis or is that a - do you think that's a
22 valid -

1 MEMBER DALRYMPLE: And are you
2 referencing the - I guess what's number three, in
3 order to assess if the exclusions are needed. We
4 assess the association between completion versus
5 refusal analyses or which analyses are we
6 specifically discussing, just so I can answer
7 correctly?

8 CO-CHAIR CROOKS: Do other committee
9 members have issues with trying to prove validity
10 that way or am I perhaps misreading it or over
11 reading the -

12 MEMBER DALRYMPLE: I mean, I can tell
13 you when I was looking at this I guess how I
14 personally felt was this doesn't help me
15 understand per se whether exclusions are needed
16 because it's showing there are differences
17 between those who complete the survey and those
18 who refuse the survey, and refusal is now part of
19 your denominator.

20 Yet there's no case mix adjustment.
21 So, for example, if we look at number three, the
22 odds of completing versus refusal and you look at

1 age, those who are older are more likely to
2 complete than refuse.

3 Those who are male are less likely to
4 complete versus refuse. If I'm interpreting this
5 correctly please other people jump in. And then
6 year - if this is year of the survey, does anyone
7 know if this is year per year of the survey?
8 That's how I -

9 DR. BRAGG-GRESHAM: That's correct.

10 MEMBER DALRYMPLE: Okay. Thank you.
11 So as the year increases there's an increasing
12 odds of completion versus refusal.

13 So then you can also look at the next
14 model, which is different facility completion
15 percentage points with respect to percent male or
16 race and also see differences.

17 So at least when I looked at this
18 table and perhaps we should give the developers a
19 chance to explain it to us this didn't help me
20 think about validity as much as is case mix
21 adjustment needed because of different
22 populations within different facilities if

1 refusing is now in the denominator.

2 So for me personally it raised more
3 questions than it answered, Peter. But perhaps I
4 didn't fully understand the intent.

5 There's also completed versus excluded
6 but the part I was most interested was completed
7 versus refused because of the denominator
8 changes.

9 So perhaps we should give the
10 developers the opportunity to inform us how they
11 intended us to think about it in case we're
12 missing the primary goals.

13 CO-CHAIR CROOKS: Does the developer
14 wish to comment?

15 MEMBER DALRYMPLE: Jennifer?

16 DR. BRAGG-GRESHAM: Beth - oh, so you
17 went ahead and just - so the issue here is that
18 we were unable, you know, to go in and audit the
19 patients in KDQOL complete.

20 So in discussions with NQF, this was
21 data that we had that we hoped would, I guess,
22 get at the validity question.

1 So we wanted - and I think, you know,
2 this is an exclusion so this - I think we just
3 wanted to be sure here, you know, that the case
4 mix - you know, we wanted to know if the case mix
5 was important in looking at this.

6 Beth, was there another reason that -

7 MS. WITTEN: Well, one thing that we
8 didn't have the opportunity to do was to go into
9 clinics and see if people truly did do what they
10 said they did.

11 Same thing is true for the depression
12 screen, for the pain screen. We don't even know
13 for sure that some of the other clinical measures
14 like Kt over V are measured the same way every
15 time. We're trying to do the best we can and
16 assuming that people aren't lying - people aren't
17 gaming the system.

18 This is not currently publicly
19 reported. It's not something that a clinic's
20 income is based on. So there's not maybe as high
21 a need to lie on this particular measure as there
22 might be on something that they could have their

1 funding cut. I don't know if that answers the
2 question or just goes off target.

3 MEMBER SOMERS: I think that I have to
4 agree with Laurien because I think the data
5 that's been presented here would speak towards
6 the need for some case mix adjustment because
7 depending upon the population you have shown data
8 that there are differences.

9 MS. WITTEN: So this is case - you're
10 asking for case mix adjustment on whether you
11 completed or didn't complete, not on the scores,
12 because there is actually in KDQOL complete and I
13 think Fresenius and I assume DaVita and other
14 providers there is case mix adjustment.

15 The outcomes and practice pattern is
16 set up for the scores. Case mix adjustment based
17 on age, gender and diabetes status. We're just
18 looking at the process measure of did you
19 complete it, did you not complete it.

20 MEMBER ZARITSKY: That's with the data
21 you have here, right, saying that you need to
22 adjust for completion.

1 MEMBER DALRYMPLE: But the measure is
2 not case mix adjusted.

3 MEMBER ZARITSKY: Right.

4 MEMBER DALRYMPLE: But the data
5 presented suggests it should be.

6 MEMBER ZARITSKY: Suggests it should
7 be.

8 CO-CHAIR CROOKS: Alan?

9 MEMBER KLIGER: I agree.

10 CO-CHAIR ANDERSON: Is there any
11 further discussion or questions for the
12 developers? Are we ready to call for the vote?

13 MS. OGUNGBEMI: We are now voting on
14 validity for Measure 0260. The options are one,
15 high; two, moderate; three, low; and four,
16 insufficient.

17 Voting is open. We are waiting on one
18 more vote. Could everyone just try and use their
19 clickers one more time, please? Thank you.

20 MS. BAL: Lori, we got your vote so
21 you do not need to send it again. Thank you.

22 MS. OGUNGBEMI: Thank you. Results

1 are in. Zero percent high, 10 percent moderate,
2 80 percent low and 10 percent insufficient.
3 Measure 0260 fails on validity.

4 MR. LYZENGA: So given that validity
5 is a must-pass criterion that means the measure
6 does not pass. We could still continue a bit of
7 discussion if we want. I think we have the time
8 in case we wanted to provide some feedback for
9 the developers if they wanted to bring the
10 measure back at another time.

11 Is there any additional feedback on
12 any of the remaining criteria, usability or
13 feasibility or some of these other things you've
14 discussed with respect to reliability or validity
15 or importance that you'd like to pass on to the
16 developer for other future efforts?

17 MS. SAMPSEL: And let me tease that
18 out a little bit more because as a maintenance
19 measure remember there's more importance on
20 feasibility and usability and really where this
21 measure is going.

22 You know, typically we wouldn't have

1 those discussions. We're not going to vote on
2 them.

3 But in case there is additional
4 information that might help the developer, if you
5 had noticed things in your preliminary reviews
6 and evaluations it might be helpful at this time.
7 It would just be a matter of putting it out on
8 the table so the developers would know how to
9 respond.

10 CO-CHAIR CROOKS: Laurien, did you
11 want to summarize what you thought about
12 feasibility and usability?

13 MEMBER DALRYMPLE: In terms of
14 feasibility this seemed like a feasible measure
15 and as noted by the developer their in talks with
16 CROWNWeb so that would, obviously, increase the
17 feasibility quite a bit if KDQOL data was entered
18 into CROWNWeb.

19 But my understanding from the
20 developer is a number of independent dialysis
21 organizations already participate in the KDQOL
22 complete and the LDOs tend to have their own

1 system. So from my perspective, this is a
2 feasible measure to report.

3 In terms of usability and use, it's
4 planned per the developer to be used in public
5 reporting and current uses is quality improvement
6 with bench marking within the KDQOL complete and
7 also some internals to specific organizations.

8 Did we have any committee pre-
9 evaluation comments that were relevant to
10 feasibility or usability? I'm trying to look on
11 the screen because those may be the most helpful.

12 But I don't recall there being
13 substantive concerns about either of these
14 criterion. So usability and use. Would it be
15 possible just for us to give all of those
16 comments on to the developer?

17 MS. SAMPSEL: Those are already shared
18 with the developer.

19 MEMBER DALRYMPLE: Okay. So I think
20 we probably don't need to read them aloud.

21 CO-CHAIR CROOKS: Okay. So I think
22 we're at the point where we can take a break.

1 Back in, what, 15 minutes? Ten minutes? What do
2 you suggest? Fifteen minutes. All right.

3 (Whereupon, the above-entitled matter
4 went off the record at 10:46 a.m. and resumed at
5 11:04 a.m.)

6 CO-CHAIR CROOKS: So as long as we're
7 a little ahead of schedule, let's keep pushing it
8 along and see where we can get to before lunch
9 time. And at 11:30 we have a break for public
10 comments. Before lunch? Okay.

11 So we've decided to follow the order
12 on the agenda, rather than the order that they
13 were put out initially. So we're going to move
14 to measures, the two measures on vascular access,
15 first 2977, standardized fistula ratio, and then
16 the catheter rate.

17 So John is here to present for the
18 developer. Thank you.

19 DR. SEGAL: Thank you very much for
20 the opportunity to address the group. I'm John
21 Segal. I'm a nephrologist. With me is Sehee Kim
22 who is our statistical guru who did much of the

1 modeling for our measure. And I'll read our
2 opening statement.

3 The CMS Fistula First Catheter Last
4 initiative has helped establish significant gains
5 in fistula rates over the last decade. Although
6 the literature continues to highlight the general
7 benefits of fistula compared to grafts or
8 catheters, there's been a growing concern in the
9 dialysis community that in some subsets of the
10 dialysis population increased use of grafts and
11 less emphasis on fistula may be appropriate with
12 continued emphasis on reduction in the use of
13 tunnel catheters.

14 In response to these concerns, CMS
15 called for a technical expert panel that was
16 convened in April of last year. The group
17 acknowledged that while grafts play an important
18 role in vascular access, a fistula and catheter
19 measure would be both complementary and
20 sufficient and that there was no substantial gain
21 in having a third measure to evaluate graft use.
22 In addition, the TEP recommended that we look at

1 risk adjustment strategies for fistula rates,
2 thereby accounting for patients that may be more
3 likely to end up with a graft.

4 Both vascular access measures that
5 will be discussed today represent substantive
6 revisions that reflect input from the TEP and are
7 intended to replace the existing measures that
8 were first endorsed in 2007 and then re-endorsed
9 in 2012 and last year.

10 I'd like to highlight the five major
11 changes for the fistula measure. Those include
12 risk adjustment for factors that are associated
13 with decreased likelihood of fistula success;
14 inclusion of all eligible hemodialysis patients,
15 not just Medicare beneficiaries since the measure
16 is now specified to be calculated from CROWNWeb;
17 inclusion of patients in the first 90 days of
18 dialysis who were previously excluded as this is
19 a critical time for access planning and
20 placement; including only patients with a fistula
21 that are counted in the numerator; fistula
22 combined with another access type such as a

1 catheter is no longer counted as it was in the
2 currently endorsed measure. And lastly,
3 exclusion criteria have been added to the measure
4 for conditions associated with the limited life
5 expectancy where fistula may not be the
6 appropriate choice for access. Thank you.

7 CO-CHAIR CROOKS: One clarification,
8 on the inclusion or exclusion or Medicare only,
9 it now is Medicare only or it was Medicare only
10 before?

11 DR. SEGAL: In the past, it was -- the
12 currently endorsed measure is designed to be
13 calculated either using Medicare claims or with
14 CROWNWeb, but it's typically for Medicare only.

15 CO-CHAIR CROOKS: So as it stands now,
16 this measure will only apply to Medicare-covered
17 patients?

18 DR. SEGAL: The measure that we're
19 discussing today applies to all patients.

20 CO-CHAIR CROOKS: Will be all, so it's
21 now broadened out for all.

22 DR. SEGAL: Exactly.

1 CO-CHAIR CROOKS: Okay. Thank you.
2 Okay, so Franklin knows he's sitting quietly on
3 the sidelines. Thank you. Elizabeth Evans, Alan
4 Kliger, and Debra Hain are our primary
5 discussants. Who wants to take the lead? Dr.
6 Kliger.

7 MEMBER KLIGER: Okay, so this has been
8 intended to join in the series of standardized
9 rates of all sorts of things that we're currently
10 measuring. It's just interesting to point out at
11 the outset that as a standardized rate that by
12 definition we're always comparing current
13 performance with what expected performance would
14 be, rather than an absolute rate. And we brought
15 this up before, but I just want to raise that
16 again for anyone who may want to make any
17 comments about that.

18 And as we just heard, the numerator is
19 the adjusted count of adult patient mumps, using
20 an AV fistula as the sole means of vascular
21 access. The denominator, all patients 18 years
22 old, as of the first day of the reporting month,

1 on maintenance hemodialysis in center and home
2 hemodialysis.

3 And the denominator exclusions and
4 I'll just -- I want to just pause and go over
5 those just now. We'll talk about that again when
6 we talk, I guess, about the validity, but I want
7 to highlight some of specifics here. It's
8 excluding children, 18 years or younger. It's
9 excluding peritoneal dialysis and it excludes
10 patients with incident or home hemodialysis but
11 less than the complete month at the same
12 facility. So it's really just that one month
13 window at that same facility.

14 In addition, the folks putting this
15 together specifically wanted to eliminate
16 patients with a catheter that have a limited life
17 expectancy. And the way that they define that
18 was patients under hospice care in the current
19 reporting month; patients with metastatic cancer
20 in the past 12 months; patients with end-stage
21 liver disease in the past 12 months; and patients
22 with coma or anoxic brain injury in the past 12

1 months.

2 And rather than do case mix
3 adjustment, it sounds like you guys decided to
4 make those exclusions because of the variation in
5 the percentage of those patients across the
6 spectrum that there were different distribution
7 of those patients at different dialysis
8 facilities, so chose to make those exclusions
9 rather than adjust for the presence of those
10 diseases.

11 So if you look first -- if we look
12 first at the evidence to support the measure,
13 I'll make some comments, but then I'll be really
14 interested to hear what everyone else thinks
15 about this. There's really clear evidence as the
16 developer just said and it continues to grow that
17 there's a relationship between AV fistula use and
18 better outcomes and fewer complications. I note,
19 however, that the studies are all retrospective
20 and observational studies and while those are
21 obviously very important to help us think about
22 problems, they are retrospective and they're on a

1 population level. And so I think we just have to
2 be conscious that that's the case.

3 And this time for the first time,
4 we're being asked to exclude these classes of
5 patients that I discussed, but there is no
6 discussion of other potential subsets of patients
7 who might also perhaps not benefit from a
8 fistula; for example, patients who make a choice
9 based on their own judgment of what access they
10 should have. Now, we could make inferences based
11 on the data that's been published, but unless the
12 developer can help, I don't remember any studies
13 that specifically looked at patient choice and
14 looking at that subset of population that makes a
15 decision to use something other than a fistula.
16 And we all know that there are, of course, such
17 patients that are there. So it's just unknown.
18 We don't really know that. The frail elderly or
19 patients with very poor vascular access, very
20 poor potential vascular structures to construct
21 an access.

22 So at least to me, the exclusions seem

1 very reasonable and appropriate and I, for one,
2 was really glad to see you exclude those, but I
3 wonder about other potential exclusions that you
4 haven't considered.

5 In any case, in terms of looking at
6 overall the data to support the measure, I think
7 the data are strong, but since they are
8 observational and retrospective, I have just -- I
9 wouldn't rate it as the very highest level of
10 data.

11 So let me just ask others in terms of
12 specifically the evidence to support the measure,
13 if there are other comments.

14 MEMBER GREENSTEIN: I just want to
15 make a comment to what you said, Alan. I think
16 that you could also make the point to exclude
17 those patients that the access surgeon says it's
18 impossible to create fistula graft, because
19 otherwise if you don't exclude them, you're going
20 to be including them in your denominator all the
21 time.

22 And there are patients like that. I

1 mean I face that every once in a while when a
2 patient is like you said, elderly, 80 year old,
3 and has really poor veins and, you know, to put a
4 graft in this person, the skin is going to just
5 rip apart every time you stick the saline with a
6 hemocatheter.

7 MEMBER KLIGER: Yes. So perhaps I can
8 ask the developer, did you examine the
9 distribution of those patients across all? Is
10 there even distribution or not of patients where
11 the potential of establishing an access is
12 exceedingly low?

13 DR. SEGAL: The short answer to the
14 question is no, we don't have that data
15 available, but the TEP spent an enormous amount
16 of time discussing patients who had exhausted all
17 of their anatomic options for access and through
18 this uniform agreement that that would be an
19 important exclusion criteria for this measure,
20 where we got the TEP was unable to reach
21 consensus in how best to implement that concept
22 or construct. And so there was discussion about

1 an attestation from the facility and who should
2 make that attestation and how often should it be
3 done and we couldn't reach an agreement about a
4 best process to put into place.

5 What I will say is that with vascular
6 access data now accumulating in CROWNWeb, I see
7 that in the future we might be able to go and
8 look back and say oh, this patient's had three
9 failed fistulas and two grafts and now they're
10 dialyzing with a catheter and so we may be able
11 in the future to look at people who have gone
12 through multiple accesses or exhausted their
13 options to be able to potentially exclude from.
14 We just don't have that depth of data available
15 to us right now.

16 CO-CHAIR CROOKS: But if one argues
17 that they're evenly distributed through different
18 facilities, maybe that's not all that important.

19 MEMBER KLIGER: Right, but Peter, we
20 don't have the evidence for that --

21 CO-CHAIR CROOKS: Right.

22 MEMBER KLIGER: -- so we really don't

1 know.

2 CO-CHAIR CROOKS: Right.

3 MEMBER GREENSTEIN: I don't think they
4 are evenly distributed. Just from my own
5 experience from working in the Bronx, I mean I
6 know there's one facility that -- this facility
7 has mostly nursing home patients and they're
8 train wrecks in terms of access.

9 MEMBER KLIGER: In any case, that
10 probably comes to the validity discussion, but in
11 terms of the -- any other concerns or questions
12 or comments about the evidence?

13 CO-CHAIR CROOKS: So I think we can
14 vote on evidence then. Let's put the question.

15 CO-CHAIR ANDERSON: Are there any
16 other comments from the other reviewers other
17 than what Alan --

18 MEMBER EVANS: Sorry, speak.
19 Intermediate clinical outcome measure. Okay.
20 That was all.

21 MS. OGUNGBEMI: We are now voting on
22 the evidence for measure 2977, hemodialysis

1 vascular access standardized fistula rate. The
2 options are 1, high; 2, moderate; 3, low; and 4,
3 insufficient. Voting is open.

4 (Voting.)

5 MS. BAL: Could everyone just vote one
6 -- I'm sorry, never mind, 19 is the right number.
7 Thank you.

8 MS. OGUNGBEMI: The results are for
9 evidence: 26 percent high; 74 percent moderate;
10 0 percent low; and 0 percent insufficient,
11 measure 2977 passes on evidence.

12 MEMBER KLIGER: Okay, thanks. We talk
13 about the performance gap. It continues to amaze
14 me as I look at the data that you presented that
15 despite evidence of -- despite shining a light on
16 this for the last at least nine or ten years,
17 that there continues to be very convincing
18 evidence for a performance gap and for
19 disparities in care both. And the data we're all
20 presented here and you've all had a chance to see
21 that, but it does indeed look like the
22 interquartile differences in measure performance

1 from CROWNWeb are substantial and that there are
2 demonstrated disparities by age, sex, ethnicity,
3 race, political party.

4 So I think that you did deal with
5 those issues and we have clear evidence of a
6 performance gap and disparities. So the other
7 two major reviewers, can I ask you if you have
8 any other comments? And then anybody else?
9 Okay.

10 CO-CHAIR ANDERSON: All right, are we
11 ready to vote? Good.

12 MS. OGUNGBEMI: We are now voting on
13 performance gap for measure 2977. The options
14 are 1, high; 2, moderate; 3, low; and 4,
15 insufficient. Voting is open.

16 (Voting.)

17 MS. OGUNGBEMI: Results are for
18 performance gap of measure 2977: 53 percent
19 high; 42 percent moderate; 5 percent low; and 0
20 percent sufficient. Measure 2977 passes on
21 performance gap.

22 MEMBER KLIGER: So we come to

1 reliability. The developers measured reliability
2 by calculating the inter-unit reliability. This
3 is a measure we're all familiar with. We've
4 talked about that our last round and we will for
5 other measures here as well.

6 And here, the inter-unit reliability
7 was 74 percent, .74, suggesting that three
8 quarters of the observed change was -- can be
9 assessed by this variable and noise is the other
10 25 percent. So by this measure, that's a pretty
11 darn good test of reliability.

12 First, do any of the other two
13 developers have any questions about that? Not
14 developers, I'm sorry, reviewers and others.

15 MEMBER DALRYMPLE: Were we going to
16 discuss specifications first or were we going to
17 do that next?

18 MEMBER KLIGER: I wanted to do that
19 after this.

20 MEMBER DALRYMPLE: After the IUR,
21 okay.

22 MEMBER KLIGER: Yes. Okay, so then

1 when we get to talk very specifically about these
2 specifications, let me just open that and ask
3 people for their comments. I've actually already
4 made mine. So first, the other two who were
5 major reviewers, any comments about the
6 specifications?

7 MEMBER EVANS: I had issues with
8 really the clinics that have that high elderly
9 patient population that have no vessels and is
10 that going to skew their numbers with that for
11 that validity for that particular clinic because
12 they do live in certain areas and they will
13 attend a higher percentage at certain clinics.

14 MEMBER KLIGER: Lorien, did you have
15 something?

16 MEMBER DALRYMPLE: So I had several
17 questions about the specifications primarily
18 focused on the exclusions.

19 The first point I guess I would make
20 is my understanding then of the exclusions is
21 they can truly only be applied to Medicare
22 recipients, but this measure includes all

1 patients within a facility. So it's not clear to
2 me if there's some accounting in the model for
3 proportion of patients represented by Medicare
4 within the facility to try and offset arguably
5 the bias in your ability to capture an exclusion
6 so we could ask the developers to answer that.

7 And then although --

8 MEMBER KLIGER: Can you stop just with
9 that? Let's just ask them that question first.

10 MEMBER DALRYMPLE: Sure.

11 DR. SEGAL: Sure, that's a great
12 question. So when we look back to look for
13 exclusion criteria, so really we're looking for
14 people that have either hospice or Medicare
15 claims.

16 So when we look back, we find that 84
17 percent of patients have at least 1 Medicare
18 claim in the last 12 months. So that you're
19 correct, there are 16 percent of people that we
20 have no information that these exclusion criteria
21 will be extrapolated to. But here's the key
22 point, when we look at facilities as a function

1 of what proportion of Medicare patients do they
2 have, we broke it into essentially three groups:
3 facilities that have less than 50 percent
4 Medicare patients. Those are very, very few in
5 number. We split it then to 50 to 75 percent
6 Medicare patients and 75 to 100 percent of
7 Medicare patients in the facility.

8 And when we looked at whether these
9 adjustments that we're making in the model change
10 our standardized fistula rate, we found no
11 difference. So what that means is at the
12 individual level, having individual patient level
13 doesn't seem to have an impact on the facility
14 model. So the facility standardized fistula rate
15 didn't change when we had a small group of
16 patients that either had or didn't have
17 comorbidity or exclusion criteria.

18 MEMBER DALRYMPLE: And did that
19 finding surprise you? That in facilities with
20 extremes such as less than 50 percent Medicare
21 patients that they -- that the estimate wasn't
22 influenced by --

1 DR. SEGAL: Sorry, we're not talking
2 about the facilities. Since there are so few
3 facilities, there were less than 50 percent. So
4 in the 50 percent or more -- so the vast majority
5 of facilities, there's very little difference
6 when you have a few patients that don't have that
7 information.

8 So I interpret that to mean that our
9 model is relatively robust and that having a few
10 patients one way or the other isn't going to sway
11 the overall impact of the facility analysis.

12 MEMBER KLIGER: Anyone else have
13 comments about these exclusions or anything about
14 these specifications?

15 MEMBER DALRYMPLE: I had a separate
16 comment about the exclusions that I thought maybe
17 other committee members would have thoughts on,
18 and if not, we could go to the developers. But
19 when I looked at that ICD-9 specifications it was
20 unclear to me if they fully captured the picture
21 of, for example, metastatic cancer or what was
22 intended by that, for example. I think we have

1 ICD-9 codes for ALL and AML, but I didn't see any
2 for lymphoma.

3 So again, how were ICD-9 codes
4 selected to represent what is or is not
5 metastatic cancer and then fairly select codes
6 were selected to end-stage liver disease, whereas
7 the number of codes that include cirrhosis were
8 left off and perhaps that was appropriate and
9 intentional but the process for selecting ICD-9
10 codes was unclear to me, as was the process for
11 ICD-10 crosswalking, if that was simply done
12 using GEMs or if there were actually coding
13 expertise used to supplement that ICD-10
14 crosswalk.

15 DR. SEGAL: So we used HCC groupers
16 for the specific ICD-9 codes. So we didn't go in
17 and one by one isolate ICD-9 codes for these
18 diagnoses. So there are large categories for
19 metastatic cancer, for liver disease. And so we
20 just used those as a starting point and we didn't
21 really modify them to add or take out from those
22 groupers.

1 MEMBER DALRYMPLE: For the ICD-10
2 crosswalk, you used an ICD-10 version of the HCC
3 essentially or how was that done?

4 DR. SEGAL: Right. We have a
5 crosswalk process that moves those over. So
6 obviously, since all of the modeling that we've
7 done has been based on ICD-9 codes, we haven't
8 had a chance to -- we are not yet able to test
9 the ICD validity in terms of that crosswalk.

10 MEMBER KLIGER: In terms of racial
11 differences and gender differences, the
12 specifications do not state anything about
13 adjusting for that. So you're not trying to
14 adjust for those and would that be appropriate
15 not to adjust?

16 DR. SEGAL: Correct. In the current
17 model, we are not adjusting for race or sex. It
18 was -- after reviewing the literature, so for
19 example, there are some studies that report that
20 women have lower rates of fistula than men. Some
21 of those studies looked at forearm fistulas and
22 other studies looked at upper arm fistulas, show

1 that there were no differences. And so we are
2 trying to be cautious that we don't adjust for a
3 factor that may represent a disparity in care as
4 opposed to a true biologic difference.

5 CO-CHAIR CROOKS: I would agree that's
6 appropriate. Other comments on specifications?

7 CO-CHAIR ANDERSON: To the measure
8 developer, when you were looking at it in your
9 TEP panels, did you consider people that have had
10 vein mapping, and to Stuart's comment, that were
11 ineligible for a permanent access as a means of
12 having an exclusion criteria for these fragile
13 patients that don't -- or aren't going to have an
14 access?

15 MEMBER GREENSTEIN: Can I add on top
16 of that? The IV drug abusers, dependent upon
17 where you live, they are the most challenging
18 patients in the world. So shouldn't they be
19 possibly excluded also then?

20 DR. SEGAL: For those, we are -- those
21 are all considered in our adjustment for the
22 model, so we adjust for older age. We adjust for

1 nursing home status as a marker potentially for
2 frailty. We do adjust for IV drug use. So we
3 did not specifically discuss at the TEP. I don't
4 recall issues like vein mapping in particular as
5 a way of identifying people who might be excluded
6 from the measure outright.

7 MEMBER GREENSTEIN: I personally would
8 not use vein mapping because every vascular lab
9 is going to be totally different in terms of --
10 it's very technician-specified. I know I just
11 get vein mapping, not for the veins, but should
12 look at the arteries actually.

13 CO-CHAIR CROOKS: Okay. Let's vote on
14 reliability and then I guess because of the
15 overlap with specifications in the validity, some
16 issues may come up there as well. I think we can
17 vote on reliability at this point. IUR was 74
18 percent.

19 MS. OGUNGBEMI: We are now voting on
20 the reliability of measure 2977. Options are 1,
21 high; 2, moderate; 3, low; and 4, insufficient.
22 Voting is open.

1 (Voting.)

2 MS. OGUNGBEMI: Results are for
3 reliability of measure 2977: 21 percent high; 79
4 percent moderate; 0 percent low; and 0 percent
5 insufficient. Measure 2977 passes on
6 reliability.

7 MEMBER KLIGER: Okay, so then going
8 along to validity, the developers correlated this
9 particular measure with standardized mortality
10 rate and standardized hospitalization rates and
11 as I'm sure no one was surprised by in this room,
12 the correlations were there and were good.

13 They did some additional validity work
14 using regression models and I can only say that
15 the validity testing, at least as proposed, is
16 reasonable and is strong. So I believe the
17 validity there is high.

18 In terms of the specifications or
19 exclusions and the validity testing, let me just
20 again open that to any other discussion. First,
21 from our other reviewers, in terms of overall
22 validity, and specs and then I'll open it up for

1 everybody.

2 MEMBER EVANS: I do want to point out
3 one thing from the TEP that they put in a little
4 caveat that it was recognized that some patients
5 on dialysis will need to have a graft or even a
6 catheter. As evidence, the CMS AV fistula
7 targeted the facility level is 68 percent rather
8 than 100 percent which recognizes a third of
9 patients will require a different type of access.

10 They do say the TEP recognized that
11 while fistulas are preferred, an unintended
12 consequence of a fistula measure that doesn't
13 account for a patient's overall health status
14 could harm patients by subjecting them to fistula
15 surgery.

16 MEMBER KLIGER: Okay, any other
17 comments from anybody? Questions?

18 MEMBER DALRYMPLE: I had a question
19 for the main reviewers. What did you think about
20 the percent excluded? Was it what you would have
21 expected or -- I'll give you my bias. It seemed
22 low to me to be honest. I had anticipated a

1 higher percent exclusion.

2 MEMBER KLIGER: So I shared your
3 surprise. I thought it was low, but I guess
4 that's reassuring to me.

5 MEMBER DALRYMPLE: If I can ask the
6 developers, did you think the exclusions were
7 what you would have anticipated among this
8 population and is there any concern that there
9 are unselected HCC categories or something else
10 accounting for the low percentage of exclusions
11 based on the descriptions?

12 DR. SEGAL: I agree, when I first saw
13 those numbers, it was a bit lower than what I was
14 anticipating finding as well, but we didn't --
15 after doing a couple of different analyses, to
16 make sure that we think we're really measuring
17 what we're measuring, we think we are. And so
18 there again, there is some range. There are
19 obviously facilities that have much higher
20 proportion of patients that are excluded, but
21 overall, it's relatively low.

22 MEMBER KLIGER: And again, to me the

1 issue again is that I think the exclusion
2 criteria that you picked are defensible and are
3 real. I'm just concerned about as we had some
4 discussion, other subgroups that might not be so
5 evenly distributed and might likewise be
6 considered for exclusion.

7 However, I think that at least in my
8 mind, it's likely that the patients that you've
9 chosen to exclude are the largest bulk of those
10 that we would end up seeing as an excluded link.

11 DR. SEGAL: One other comment about
12 the exclusions. When we first looked at
13 exclusion criteria, we looked at them and --
14 blinded to their access type. So what we found
15 is many patients who met exclusion criteria were
16 dialyzing with fistula. So they were in hospice.
17 They had a fistula or they had metastatic cancer
18 and they had a fistula. So when you narrow it
19 down to patients who just have a catheter, it was
20 a smaller number.

21 CO-CHAIR ANDERSON: Any further
22 questions? All right, we're ready to vote.

1 MS. OGUNGBEMI: We are now voting on
2 validity for measure 2977. The options are 1,
3 high; 2, moderate; 3, low; and 4, insufficient.
4 Voting is open.

5 (Voting.)

6 MS. OGUNGBEMI: Results are for
7 validity: 32 percent high; 68 percent moderate;
8 0 percent low; and 0 percent insufficient.
9 Measure 2977 passes on validity.

10 MEMBER KLIGER: Okay, feasibility.
11 Feasibility, again, just to remind everybody,
12 measures the logic of the specifications, the
13 required data that are available and the burden,
14 whether it can be implemented without burden.

15 These data -- we've had lots of
16 experience capturing and examining these data and
17 so there is nothing new here. So I have no other
18 comments in general about the feasibility, but
19 invite anybody else.

20 CO-CHAIR ANDERSON: No further
21 comments. Let's vote.

22 MS. OGUNGBEMI: We are now voting on

1 the feasibility of measure 2977. The options
2 are: 1, high; 2, moderate; 3, low; and 4,
3 insufficient. Voting is open.

4 (Voting.)

5 MS. OGUNGBEMI: Results are 84 percent
6 high; 16 percent moderate; 0 percent low; and 0
7 percent insufficient. Measure 2977 passes on
8 feasibility.

9 MEMBER KLIGER: Okay, flying along
10 here, when we talk about usability and use, again
11 to remind everybody, this is the extent to which
12 audiences including consumers, purchasers,
13 providers, policy makers, maybe even doctors, use
14 or could use performance results for both
15 accountability and performance improvement
16 activities.

17 The comments that most people said is
18 that these have been used. The fact that we're
19 using statistically and standardized rates is the
20 issue that at least some have raised, whether or
21 not this ought to be calculated as a standardized
22 ratio or whether they ought to be calculated as

1 an absolute amount is something I just want to
2 open and ask people for their thoughts about
3 that.

4 Other than that -- other than moving
5 to a standardized ratio, the usability has been
6 really clear before in any case. So in terms of
7 usability and use, let me open first to the other
8 major reviewers and then to everybody else. You
9 guys have a comment about that? And then anybody
10 else.

11 MEMBER NARVA: I assume this has a
12 relatively low exclusion rate, so that reduces
13 the need to have a standardized -- make a
14 standardized ratio. Is that true?

15 MEMBER KLIGER: Ask the developers
16 that question.

17 DR. SEGAL: If you had a higher
18 exclusion rate, then there would be greater need
19 to have a standardized ratio. Is that ==

20 MEMNER KLIGER: Let me just clarify to
21 make sure I understood actually the first part.
22 So this measure is calculated as a rate, not as a

1 ratio. So we felt that was important so that
2 facilities are used to seeing their fistula rate.

3 And so we didn't want to change the
4 game for them midstream and say now it's a ratio
5 and you don't exactly know what your percentage
6 is when it's adjusted. So I'm not sure if that
7 changes the question, but the facilities will
8 have a rate as expressed as a percentage that is
9 reported.

10 MEMBER NARVA: My question was just if
11 there were a higher exclusion rate, it would
12 suggest that there's more opportunity to have
13 variation between units based on what the
14 population is and more need to have -- express it
15 as a ratio. So this has a low exclusion rate, so
16 the need to even think about doing it as a
17 standardized rate is not as great. Is that -- do
18 I get it? Is that fair to say, the ratio?

19 DR. SEGAL: I think sometimes we think
20 about rates and ratios as a function of event
21 occurrences, so that for at least the way we did
22 our standardization, we felt that the rate for

1 this measure was most appropriate because access
2 is a frequent -- you know everybody has got an
3 access as opposed to other measures which have
4 more rare events where sometimes a ratio is more
5 helpful to look at that.

6 MEMBER KLIGER: I apologize that I
7 introduced that confusion, so I'm sorry. Indeed,
8 it is a rate and not a ratio. Thank you.

9 CO-CHAIR CROOKS: It says that CMS
10 will consider using this and then return the
11 other related measures. Are you beyond
12 considering -- is this definitely the plan to use
13 this?

14 DR. SEGAL: I can't speak for -- well,
15 Joel can -- CMS can speak for CMS.

16 CO-CHAIR CROOKS: Assuming it's
17 endorsed, is it a pretty sure thing it will be
18 used?

19 MEMBER KLIGER: Can we invite you to
20 speak? You have to leave your Social Security
21 Number at the door though.

22 DR. ANDRESS: Understood. I'll do

1 that on my way out. Okay, so we developed these
2 measures specifically with the intention of
3 updating the existing vascular access measures.
4 When you look at them, they were developed in
5 2007 and we see this as a natural progression of
6 those measures.

7 Nothing is ever set in stone. I have
8 to caveat that every time someone asks me about
9 the QIP obviously. There's a rulemaking process.
10 These measures in order to go into the QIP will
11 have to go to the MAP first and we'd have to get
12 feedback there and it would have to go through
13 rulemaking.

14 We also have a process in place now
15 for including measures on Dialysis Facility
16 Compare, and we would have to go through that
17 before it was set, but I think we developed these
18 with the intention that these would be our
19 vascular access quality measures in the future.
20 Whether or not they actually become so depends on
21 a great deal of action in the coming year or two.

22 MEMBER GREENSTEIN: I have a question.

1 So I'm not clear then, what is the role then?
2 Because you will have dialysis units that are
3 going to be totally at extremes. The dialysis
4 unit that has only the nursing home populations,
5 it's going to have a very low fistula rate,
6 whereas those that have the young people may have
7 a fantastic fistula rate. So what are you going
8 to do with the information then? Spank the older
9 one?

10 DR. ANDRESS: I think our intention is
11 that we developed the measure so that it can
12 capture more appropriately some of these issues
13 that have been raised with regard to facilities
14 that are treating patients who may not be
15 appropriate for fistula use while still
16 recognizing that the predominance of the evidence
17 would suggest that fistula usage is appropriate
18 for most patients. And so that's why we had the
19 genesis of the risk adjustment put in place.

20 So the adjustment is really designed,
21 as John noted, to account for variation that
22 results from patient characteristics along those

1 lines. So if you have a facility that treats a
2 lot of patients that are captured within the risk
3 adjustment, then the risk adjustment will account
4 for the facility's performance that is a result
5 of those -- the patients' characteristics.

6 MEMBER GREENSTEIN: But then shouldn't
7 you put in all the exclusions, the additional
8 ones that we mentioned? The patients that you
9 know you cannot create a fistula so that one
10 should be excluded. The IV drug abusers that you
11 know that has very poor veins, therefore that
12 should be excluded also? Otherwise, you're
13 going to -- units will be at extremes again.

14 DR. ANDRESS: So I think we've
15 discussed this to some extent. I think the point
16 to be made is that we're not -- we aren't able to
17 capture some of the information that's been
18 discussed, so we were talking -- we were all
19 talking previously about patients who have
20 exhausted all vascular access options. We don't
21 necessarily have the data to be able to capture
22 that.

1 I think from a policy perspective, we
2 still think that addressing vascular access is a
3 sufficient quality issue that we are comfortable
4 moving forward with the measures that we've
5 presented here and that they, in fact, give us
6 the opportunity to grapple with that information
7 in the future and that that can be addressed
8 through future measure maintenance as the
9 measures mature and as the data mature.

10 DR. SEGAL: And if I can just add that
11 some of the -- at the extremes, some facilities'
12 fistula rates change by up to 10 percent. So if
13 your fistula rate goes up by -- your standardized
14 fistula rate goes up by 10 percent, that sends a
15 pretty strong signal that your patient population
16 is very different than the national average that
17 we're adjusting to.

18 MEMBER KLIGER: I guess the one last
19 thing, again, as a modest concern I have, but
20 still is nagging at me is that we've never
21 analyzed patients by their choice.

22 So if you take the 85-year-old woman

1 who has been through three procedures before, who
2 says doctor, I just don't want to have another
3 operation, I don't know that we've used -- in the
4 multiple factors we have to consider for case mix
5 adjustment, we haven't talked about patient
6 choice. So I just think that's important to
7 recognize.

8 The other thing is that the unintended
9 consequences always can be patients being coerced
10 or patients in subgroups that may not have a
11 substantial advantage with a fistula being
12 coerced into getting that operation or series of
13 operations when we don't have evidence in that
14 subgroup that it is helpful, for example, the
15 frail elderly.

16 And I understand you have the case mix
17 adjustment to look at it, I just think it's
18 important to remember that there can be
19 unintended consequences at the sharp end -- at
20 the front end as we take care of those patients.

21 MEMBER HARTWELL: This is Lori
22 Hartwell. I just want to make a comment just

1 because it came up at the last meeting, but a few
2 of our members are having trouble finding a
3 skilled surgeon and they've had some bad
4 experiences with fistula placement, so I don't
5 know if that's making -- I'm sure it's -- you
6 know making their decision for them, I don't want
7 to have another fistula incision. I've had a bad
8 experience. I'm going to keep a catheter.

9 MEMBER KLIGER: So just the last for
10 me, just personally having considered all of
11 those issues in usability and use, I still
12 personally think that this is very usable and of
13 substantial use.

14 CO-CHAIR CROOKS: Not to make the
15 perfect the enemy of the good in a sense, right?
16 Okay. Are we ready then to vote on use and
17 usability? Let's do that.

18 MS. OGUNGBEMI: We are now voting on
19 usability and use for measure 2977. Your options
20 are 1, high; 2, moderate; 3, low; and 4,
21 insufficient. Voting is now open.

22 (Voting.)

1 MS. OGUNGBEMI: Results are 37 percent
2 high; 63 percent moderate; 0 percent low; and 0
3 percent insufficient. Measure 2977 passes on
4 usability and use.

5 CO-CHAIR CROOKS: Thank you,
6 committee. We're moving along on agenda or --
7 I'm sorry, let's do an overall vote. Thank you.
8 And then we'll do the public comments and then
9 maybe lunch. Okay. Just to motivate. Okay,
10 please go ahead.

11 MS. OGUNGBEMI: We are now voting on
12 the overall suitability for endorsement for
13 measure 2977. Your options are 1, yes; and 2,
14 no. Voting is open.

15 (Voting.)

16 MS. OGUNGBEMI: Results are 100
17 percent yes, 0 percent no. Measure 2977 passes
18 on its recommendation for endorsement.

19 CO-CHAIR CROOKS: So that's why I was
20 saying, why vote, you know?

21 Okay. Thank you very much. So let's
22 do our -- let's hear from the public now. We

1 have -- we can open up the line for now.

2 MR. LYZENGA: Operator, can you open
3 the lines for public comment.

4 OPERATOR: Yes, sir. At this time if
5 you'd like to make a comment please press star
6 and the number 1.

7 (Pause.)

8 OPERATOR: There are no public
9 comments at this time.

10 MR. LYZENGA: Do we have any comments
11 from the back of the room?

12 MEMBER MADDUX: Since I had to recuse
13 myself, I have to make a public comment. I would
14 just like the measure developers to think a
15 little bit. Their variety of stem cell derived
16 and other kinds of vascular material that's
17 coming to the fore that may be difficult to
18 classify between fistula and a graft. And I
19 think it would be wise to begin to think about
20 how to categorize these as we move forward.

21 Not directly related to -- well,
22 related to this measure, not in the next year,

1 probably, but as this measure gets itself into
2 play, these hybrid devices might well be
3 available.

4 CO-CHAIR CROOKS: All right, if
5 there's no more public comments or recused
6 committee member comments, we'll break for lunch
7 and reconvene at what time? Approximately 12:30.
8 Okay. Thank you.

9 (Whereupon, the above-entitled matter
10 went off the record at 11:52 a.m. and resumed at
11 12:16 p.m.)

12 CO-CHAIR ANDERSON: So, are we ready
13 for discussion of Measure 2978, the Hemodialysis
14 Vascular Access Long-Term Catheter Rate? And
15 that is Fred, Myra, and Michael Somers.

16 Who would like to go? Okay, thanks.

17 MEMBER SOMERS: So, this is Measure
18 2978 looking at long-term catheter rates. It is
19 an intermediate clinical outcome measure,
20 facility-level.

21 In the rationale, we are told that,
22 among prevalent maintenance hemo patients in the

1 U.S., catheter use has declined from 28 percent
2 to 18 percent from 2016 until the summer of 2015.
3 Yet, the percentage of patients using catheters
4 for more than three months has not shown a
5 similar decline, only going down by about a point
6 from 12 percent to 10.8 percent.

7 The numerator of the measure is the
8 number of adult patient-months in the denominator
9 on maintenance hemodialysis using a catheter for
10 more than three months or equal to three months
11 as of the last hemodialysis session of the month.
12 And the denominator is patients greater than or
13 equal to 18 years of age on the first day of the
14 month on maintenance in center or home HD.

15 Exclusions to the denominator include
16 pediatric patients, PD patients, less than a
17 month at facility, and similar to the last
18 measure we discussed, having a limited life
19 expectancy in terms of being in hospice,
20 metastatic cancer, end-stage liver disease or
21 coma, hypoxic brain injury in the last 12 months.

22 Moving on to evidence, there are 12

1 studies that are initially presented spanning
2 between 1991 and 2004. Most of those are
3 retrospective and observational, looking at whole
4 groups and not necessarily subpopulations. And
5 then, there is updated with 13 more recent
6 reports in the literature. Seven of those are
7 reviews or systematic reviews; three are opinion
8 pieces; two are observational retrospective
9 presentations, and one is a decision analysis.

10 Again, I think similar to our
11 discussion for the last measure, when you look at
12 the evidence, although the most compelling
13 evidence is retrospective and observational,
14 overall, my opinion of the evidence was that it
15 met the moderate criteria.

16 Anyone have any other questions,
17 discussion points on that?

18 (No response.)

19 CO-CHAIR CROOKS: Shall we go ahead,
20 then, and vote on evidence at this point?
21 Everybody ready?

22 MS. OGUNGBEMI: We are now voting for

1 Measure 2978, evidence, Hemodialysis Vascular
2 Access Long-term Catheter Rate. Your options are
3 1, high; 2, moderate; 3, low, and 4,
4 insufficient. Voting is open.

5 (Voting.)

6 MS. BAL: Lori, have you rejoined the
7 call?

8 (No response.)

9 I don't think she has rejoined. So,
10 we will stop it here.

11 MS. OGUNGBEMI: So, having 18 votes,
12 our results are 22 percent high, 78 percent
13 moderate, zero percent low, and zero percent
14 insufficient. Measure 2978 passes on evidence.

15 CO-CHAIR CROOKS: So, we broke the
16 protocol a little bit, I guess. You are sitting
17 here waiting to speak, and we just went right
18 past. So, I would like to pause now.

19 (Laughter.)

20 I think maybe it is best not to say
21 anything.

22 (Laughter.)

1 But I would like to pause now, give
2 you a chance to tell us why you developed this
3 and any other information you would like to
4 share.

5 DR. SEGAL: Actually, I'm okay waiving
6 my right to an opening statement.

7 (Laughter.)

8 No, I appreciate the opportunity.
9 Really, much of what we have discussed,
10 obviously, in the prior measure applies to this
11 one, including my introductory comments.

12 I am happy to highlight a couple of
13 the differences between the catheter measure that
14 the group is considering today versus the
15 currently-endorsed one, and I will just leave it
16 at that. And they are actually the same
17 similarities as to the prior measure.

18 So, similar to the fistula measure,
19 again, this measure applies to all eligible
20 hemodialysis patients, not just Medicare
21 beneficiaries, again, using CROWNWeb as our
22 datasource.

1 The second main point is that patients
2 using a catheter, even if combined with a
3 fistular graft, are now counted in the numerator
4 of this measure. So, it is similar in the last
5 measure in the denominator; now in this measure
6 it is in the numerator. And that is different
7 than the currently-endorsed measure. And then,
8 the exclusion criteria which we have discussed
9 are also being applied here.

10 So, thank you.

11 CO-CHAIR CROOKS: All right.

12 Discussion of the performance gap.

13 MEMBER SOMERS: Okay, for the gap, we
14 are provided with information from CROWNWeb as of
15 2014. It shows a range of patients in units with
16 catheters going from zero percent to 58 percent,
17 with a median of 10.5 percent interquartile, from
18 7 percent to 14.9 percent, and a mean of 11.6
19 percent. So, it does look as if there is this
20 population who continues to have catheters. And
21 as I alluded to at the beginning, the number of
22 patients still with catheters for more than three

1 months has not declined by much over the last
2 decade.

3 There is also some disparities data
4 that is given to us that shows that women are 55
5 percent more likely to have catheters. Older
6 patients of greater than 75 years of age or
7 younger patients less than 25 years of age are
8 more likely to have long-term catheters. Whites
9 are less likely to have a catheter. Patients who
10 have had end-stage disease for less than one year
11 are more likely to have a catheter or who have
12 had end-stage disease for more than nine years
13 are more likely to have a catheter.

14 So, again, I thought this data did
15 demonstrate that there was a gap.

16 MEMBER GREENSTEIN: Do you guys have
17 any explanation for why the 18-25-year-olds have
18 a higher catheter rate? That doesn't make sense.

19 DR. SEGAL: I don't have specifics
20 other than to tell you that it is a relatively
21 small group, obviously, of young patients. And
22 so, the question is, are these people who are

1 dialysis and have catheter in transition to
2 transplant as short-term or reasons along those
3 lines? But we don't have specific reasons for
4 why that group stands out.

5 MEMBER KLEINPETER: But do you have
6 any data on their IV drug use because that is the
7 population of our patients that are IV drug
8 users, the 18-to-25? Can you pull that data --

9 DR. SEGAL: Actually, that is a great
10 question. We have not done that analysis, but
11 that would be relatively straightforward for us
12 to do, is to look at the interaction between age
13 and IV drug use and see if that is one of the
14 things that is driving that.

15 MEMBER KLEINPETER: Okay.

16 DR. SEGAL: Thank you.

17 MEMBER GREENSTEIN: Yes, but those
18 patients should have grafts done. They shouldn't
19 have catheters and, then, they should have a
20 lower catheter rate because a graft can be put
21 in.

22 MEMBER KLEINPETER: Just anecdotally,

1 our surgeons won't operate on them if they have
2 had any bloodstream infections and they are
3 actively using drugs.

4 MEMBER GREENSTEIN: Well, the catheter
5 is just going to be now you are just giving them
6 easy access to shoot up the drugs.

7 CO-CHAIR CROOKS: Okay. Other
8 comments about performance gap? Is there one?

9 (No response.)

10 Shall we vote?

11 MS. OGUNGBEMI: We are now voting on
12 the performance gap for Measure 2978. Your
13 options are 1, high; 2, moderate; 3, low, and 4,
14 insufficient. Voting is open.

15 (Voting.)

16 Results are 22 percent high, 78
17 percent moderate, zero percent low, and zero
18 percent insufficient. Measure 2978 passes on
19 performance gap.

20 CO-CHAIR CROOKS: Okay. Please
21 proceed, Michael.

22 MEMBER SOMERS: All right. Now on

1 reliability, in terms of specifications, I think
2 that the same discussion that we had for the last
3 measure could apply to this as well. So, I won't
4 belabor that point.

5 In terms of reliability testing, it
6 was done for centers that had at least 11
7 patients the entire year and showed IUR of 76.5
8 percent. So, fairly high IUR for the IURs we
9 have been seeing.

10 CO-CHAIR CROOKS: Okay. Other
11 comments on reliability?

12 (No response.)

13 And again, specifications I guess are
14 tying into -- does somebody have their card up?
15 Oh, Lorien? Sorry.

16 MEMBER DALRYMPLE: I just had one
17 question on the specifications. My understanding
18 is that other unknown and missing fields are
19 counted as catheter, which may be an appropriate
20 assumption. But I was wondering if we could just
21 get clarity as to why those two are being counted
22 in the catheter numerator.

1 DR. SEGAL: We include those as a
2 catheter -- first of all, the number of unknown
3 and missing is very small. So, this is not
4 particularly impactful. But we wanted to make
5 sure that, to possibly prevent gaming the system
6 if you didn't report your access, we wanted there
7 to be a strong incentive to know that, if you
8 weren't reporting your access, you were going to
9 be counted as catheter and that should be
10 motivation to make sure you are up-to-date.

11 CO-CHAIR CROOKS: Okay. Other
12 comments?

13 (No response.)

14 Okay. Let's vote on reliability then.

15 MS. OGUNGBEMI: We are now voting on
16 reliability for Measure 2978. Options are 1,
17 high; 2, moderate; 3, low, and 4, insufficient.
18 The voting is open.

19 (Voting.)

20 One of our Committee members stepped
21 out. So, we are now down to 17 votes, but the
22 results are, for reliability, 47 percent high, 47

1 percent moderate, 6 percent low, and zero percent
2 insufficient. Measure 2978 passes on
3 reliability.

4 MEMBER SOMERS: So, for validity,
5 there was a regression model done to measure your
6 facility quintile level versus the SMR and the
7 SHR, and we are given data that shows the
8 relationship is as one would hope to see with
9 higher levels of mortality and hospitalization
10 with catheter use.

11 We are also given some data in terms
12 of exclusions, and it is similar to the last
13 measure with only a very small number of patients
14 seeming to be excluded from this with 2.35
15 percent of the patients with no risk adjustment
16 performed.

17 CO-CHAIR CROOKS: Okay. We are open
18 for more comments on validity.

19 Well, Lorien?

20 MEMBER DALRYMPLE: There are only two
21 areas that I thought it would be helpful to get
22 the Committee's perspective on. One, there were

1 major differences shown with respect to vintage
2 in terms of one of the largest risks of having a
3 catheter were being incident to dialysis.

4 And then, also, I thought there were
5 differences shown with respect to type of
6 insurance, which I think is important,
7 particularly in certain regions where your
8 insurance type dictates whether you have access
9 to a vascular surgeon in a timely fashion. Even
10 within 90 days, does it happen in some regions?

11 So, since this metric is not risk-
12 standardized or adjusted, I thought we should
13 discuss that as a Committee. And I know the
14 developers put forth arguments as to why not risk
15 adjust, but I do have concerns that not taking
16 into consideration things like vintage or
17 insurance coverage don't really account for very
18 substantive differences between certain
19 facilities in any given area.

20 CO-CHAIR CROOKS: So, are you arguing
21 for an adjustment for insurance type?

22 MEMBER DALRYMPLE: I think it is worth

1 discussing whether vintage and type of insurance
2 should be accounted for when examining catheter
3 rates at the facility level because the vintage
4 data, I thought, was some of the most impressive
5 presented. And then, I need to find the page
6 with the medical coverage.

7 But, at least in my region, that is
8 probably one of the most important determinants
9 as to whether you will get timely vascular
10 access, is what type of insurance you have and
11 whether you are capitated to a group that can
12 actually provide that service, and the wait list
13 is quite long.

14 CO-CHAIR CROOKS: I would argue the
15 opposite, though, that that is why it should not
16 be adjusted away. If I am a facility and I have
17 a low result and that is because the insurance my
18 patients have isn't covering them adequately,
19 then that is my job to go back and tell this
20 insurance company, "Hey, you're killing my rate
21 here. How come up you're not able to get me a
22 vascular surgeon?" You know, it is an

1 opportunity for improvement that you need to
2 take. I wouldn't want to see somebody getting a
3 break for that.

4 MEMBER DALRYMPLE: So, you feel like
5 the facilities can negotiate with Medicaid, for
6 example, to get access to care, is the argument?

7 CO-CHAIR CROOKS: More or less, yes.
8 And you have an argument to make to the payers
9 that if they get these patients vascular access
10 upstream or sooner, as soon as they get on
11 dialysis, you are going to decrease mortality,
12 decrease hospitalizations, and decrease their
13 costs. So, you have ammunition to go talk to
14 them.

15 So, yes, there may be others in the
16 healthcare system that should be having that
17 conversation, too, but you, as a nephrologist or
18 medical director, I think you have an obligation
19 to go back to the insurers and say, "Listen,
20 you're not paying for the service that these
21 patients need."

22 The vintage may be explained by the

1 fact that there are running out of vascular
2 access sites. Is that your question, whether
3 long-term patients --

4 MEMBER DALRYMPLE: The most profound
5 effect was in those less than one, but it was
6 also seen in those greater than nine. But I
7 think the odds ratio approached four for incident
8 patients. And at least my understanding is some
9 facilities are denying placement for patients
10 with catheters. And so, there are real
11 unintended consequences, I think, potentially if
12 decisions about facility acceptance is based on
13 whether you have a catheter.

14 CO-CHAIR ANDERSON: Myra, did you have
15 a comment?

16 MEMBER KLEINPETER: So, is it possible
17 to the developer to be able to tease out that
18 information about insurance status, simply
19 because in this era where a lot of the commercial
20 entities that have participated in the Affordable
21 Care Act are pulling out of the system, this is
22 only going to be a bigger problem moving forward,

1 with a lot of people in that first 90-day period
2 not having adequate coverage to be able to get
3 the vascular access. I know in Louisiana in that
4 first 90 days it is next to impossible to get a
5 permanent access in the patient.

6 DR. SEGAL: I will just say that we
7 specifically asked the TEP about risk-adjusting
8 the catheter measuring, including for things like
9 vintage and whatnot, and the decision from the
10 TEP was not to risk-adjust this measure, out of
11 concern that it may be too likely to give
12 facilities a pass on issues that may be in their
13 control. Now I realize vintage is not one of the
14 things in the facilities control, and insurance
15 status, clearly, is a tough one to handle, but it
16 may be possible.

17 MEMBER WAGNER: I would echo some of
18 those comments. No insurance is, of course, not,
19 then, something that one can influence a payer
20 regarding, and that is a real issue in some
21 areas.

22 And I think that another part of this

1 is one would like in some patients to have the
2 opportunity to use particular surgeons, given
3 their skill set. It would be, I think, not in
4 the patients' interest to refer patients simply
5 to someone who is in the network that happens to
6 be covered by the insurance if that is not the
7 person that can potentially do the best surgery
8 for that patient.

9 CO-CHAIR CROOKS: Okay. Other
10 comments on reliability? I'm sorry, on validity
11 of the measure?

12 (No response.)

13 Are we ready to vote?

14 Seeing no dissent, let's vote.

15 MS. OGUNGBEMI: We are now voting on
16 validity for Measure 2978. Your options are 1,
17 high; 2, moderate; 3, low, and 4, insufficient,
18 and we are now back up to 18 votes because our
19 Committee member on the phone has rejoined us.
20 The voting is open.

21 (Voting.)

22 The results are 17 percent high, 72

1 percent moderate, 11 percent low, and zero
2 percent insufficient. Measure 2978 passes on
3 validity.

4 CO-CHAIR ANDERSON: Okay. Moving
5 right along, Michael?

6 MEMBER SOMERS: For feasibility,
7 again, this is exactly similar to the discussion
8 we had for the last measure in terms of
9 collecting the data and the fact that most of
10 this is already collected.

11 CO-CHAIR ANDERSON: Any questions for
12 the developer or further comments?

13 (No response.)

14 Are we ready to vote? So, we are
15 voting on feasibility.

16 MS. OGUNGBEMI: We are now voting on
17 feasibility for Measure 2978. Options are 1,
18 high; 2, moderate; 3, low, and 4, insufficient.
19 The voting is open.

20 (Voting.)

21 The results are 78 percent high, 22
22 percent moderate, zero percent low, and zero

1 percent insufficient. Measure 2978 passes on
2 feasibility.

3 CO-CHAIR ANDERSON: All right. We're
4 moving on to usability and use. Michael?

5 MEMBER SOMERS: In terms of usability,
6 as the measure steward has told us, they are
7 hoping to plan to use this measure along with the
8 other measure for planned use and QIP for DFC.

9 In terms of the comments that we got
10 from other members of the Committee, most of them
11 thought that this would be very usable and there
12 was only one comment about concerns about a
13 subset of the population for whom the catheter is
14 not a good choice, and they had some qualms about
15 the measure in that. But, again, we have
16 addressed that as, hopefully, being a small
17 proportion of most centers' population.

18 CO-CHAIR ANDERSON: Any questions for
19 the developer or further comments?

20 (No response.)

21 We are ready for the vote for use and
22 usability.

1 MS. OGUNGBEMI: We are now voting on
2 usability and use for Measure 2978. Your options
3 are 1, high; 2, moderate; 3, low, and 4,
4 insufficient. The voting is open.

5 (Voting.)

6 The results are 56 percent high, 44
7 percent moderate, zero percent low, and zero
8 percent insufficient. Measure 2978 passes on
9 usability and use.

10 CO-CHAIR CROOKS: So, let's vote on
11 the measure overall.

12 MS. OGUNGBEMI: We are now voting on
13 2978's overall suitability for endorsement.
14 Options are yes, 1; no, 2. The voting is open.

15 (Voting.)

16 MS. BAL: Lori, we are still waiting
17 for your vote. Please send it in.

18 (Voting.)

19 We received it. Thank you.

20 MS. OGUNGBEMI: The results are 100
21 percent yes and zero percent no. Measure 2978 is
22 recommended for endorsement.

1 CO-CHAIR CROOKS: Okay. We're halfway
2 done. Well, not quite because we do have the
3 opportunity today to look at the medication
4 reconciliation measures, you probably read in
5 your email, but that comes later.

6 We don't need a break yet, and we had
7 decided that we would defer the discussion on
8 harmonization and competing measures on the
9 vascular access measures until the post-meeting
10 phone call in about a week.

11 So, that being the case, we could move
12 right to Measure 2979, the Standardized
13 Transfusion Ratio.

14 CO-CHAIR ANDERSON: It is Michael,
15 Lisa, and Jess. I think Jess is out of the room.

16 MEMBER LATTS: Michael is going to
17 take the lead.

18 CO-CHAIR ANDERSON: Oh, okay.

19 CO-CHAIR CROOKS: So, first of all,
20 Joe?

21 DR. MESSANA: Yes. Good afternoon.

22 I want to preface this by saying this

1 is not a vascular access measure and I'm not John
2 Segal. So, for those of you who remember our fun
3 meeting last year, we had a lot of enjoyment with
4 a measure that was almost identical to this. I
5 anticipate a lot more fun.

6 I'm Joe Messana, a clinical
7 nephrologist at the University of Michigan.

8 Doug, do you want to introduce
9 yourself?

10 DR. SCHAUBEL: Yes. I'm Doug Schaubel
11 from the Biostatistics Department at the
12 University of Michigan.

13 DR. MESSANA: Doug did the heavy
14 lifting on the statistical analyses underlying
15 the model. This is an indirect standardization
16 model. And so, it is a ratio, not a rate,
17 because of relatively infrequent events, just to
18 clarify from the earlier vascular access
19 discussion.

20 So, just a couple of opening comments
21 that I think generally echo the comments I made
22 last year. First, one point of clarification.

1 There was really an extensive discussion last
2 year before we actually started talking about the
3 merits and limitations of a very similar measure
4 last year about whether it was an outcome, the
5 health outcome, or an intermediate outcome.

6 I want to clarify there was an
7 agreement to move forward assuming it was a
8 health outcome last year. When I prepared the
9 revised submission forms this year, after looking
10 at the NQF criteria and knowing what the results
11 of that discussion were, I submitted this as a
12 health outcome, based on that discussion and
13 moving forward. We haven't gotten any pushback
14 until today about that decision. And so, I would
15 humbly suggest that this measure be considered as
16 a health outcome based on those criteria and last
17 year's discussion.

18 Andrew, I don't know if you have
19 anything to add about that opinion.

20 MR. LYZENGA: The only thing I would
21 say is that we would affirm that this measure
22 does fall within the bounds of an outcome measure

1 under NQS definitions, which does say in some
2 situations resource use, which I think this could
3 be considered resource use, may be considered a
4 proxy for a health state. For example,
5 hospitalization may represent deterioration of
6 health status. We do think this falls within
7 reasonable bounds of that definition as NQF
8 represents it.

9 CO-CHAIR CROOKS: May I just comment
10 on that, the proposition, too?

11 DR. MESSANA: Sure.

12 CO-CHAIR CROOKS: Outcome measures
13 such as mortality or hospitalization, you say
14 that outcome is a bad thing. A transfusion is
15 not necessarily a bad thing. Is there any way to
16 set -- does the measure give us a target or give
17 us this is the best outcome?

18 DR. MESSANA: If you are asking me
19 specifically, I have actually had people argue
20 within the last six months or a year in the
21 context of the CECI that mortality wasn't
22 necessarily a bad outcome and we don't capture

1 most of the good deaths that occur.

2 I think that is the issue with any
3 outcome; it is going to be imperfect. Generally,
4 most of the literature and the guidelines, not
5 necessarily up in space, say that unavoidable
6 transfusions are not optimal anemia management.
7 There are situations where transfusions are
8 lifesaving, but the question is whether those
9 vary across providers, in particular. So, it is
10 not an answerable question.

11 CO-CHAIR CROOKS: No outcome is always
12 good or always bad.

13 DR. MESSANA: Right.

14 CO-CHAIR CROOKS: Alan?

15 MEMBER KLIGER: Andrew, can I ask your
16 help again? Because I cannot get my head around
17 this being defined as an outcome for patients.
18 If I were a patient, whether I get transfused or
19 not is a process of my care. It is not an
20 outcome that I experience. So, can you help me
21 understand how you define this as an outcome?

22 MR. LYZENGA: Again, we didn't define

1 it as an outcome; the developer did present it as
2 an outcome. We determined that it is within the
3 bounds of our definition of an outcome, which,
4 again, the sort of closest analogy I could
5 present is as a readmission measure. A
6 readmission measure is in some sense a process.
7 What it does is it marks, in some sense it serves
8 as a proxy for deterioration in a patient's
9 health status. The hospital in that case has not
10 done a good enough job of managing their care
11 after giving them discharge instructions, and it
12 results in a readmission, which, again, in many
13 cases is a positive thing. Some patients need to
14 be readmitted.

15 In this case, the transfusion would
16 serve as a marker that the patient's blood has
17 not been managed effectively. But I would defer,
18 again, to the developer to really explain their
19 rationale in doing that.

20 DR. MESSANA: So, Alan, on the
21 evidence form it talks about health outcomes and
22 it says, "events that mark use of scarce

1 resources". So, I don't believe that using it as
2 a proxy for general deterioration is an
3 appropriate argument for a health outcome.

4 But the use of scarce resources or use
5 of resources particularly where you are comparing
6 an event to no events, even if it is relatively
7 scarce events, in the NQF evidence forms they
8 talk about that as an appropriate health outcome
9 metric.

10 MEMBER KLIGER: So, that would be an
11 outcome for the healthcare system, but not for
12 the individual patient.

13 DR. MESSANA: Yes. Just like
14 hospitalization.

15 MEMBER KLIGER: No, no, but the
16 difference is hospitalization clearly is an
17 outcome for an individual patient. Getting
18 hospitalized is an event that patients would
19 prefer not to have. It is a clear outcome that
20 makes a difference to patients.

21 DR. MESSANA: Right.

22 MEMBER KLIGER: But getting a dialysis

1 treatment or a transfusion or a cardiac
2 catheterization are not outcomes.

3 DR. MESSANA: Giving a transfusion
4 that precludes access to kidney transplantation,
5 or something like that, I think should be viewed
6 as an outcome for a patient.

7 MEMBER LATTS: I would tend to agree
8 that this would be considered an outcome in how
9 we are thinking of outcomes in performance
10 measurement. For example, the process is the act
11 of measuring whether or not you had the test
12 done. So, whether or not you had your hematocrit
13 drawn, whether or not you had your A1C drawn --
14 whereas the outcome in diabetes care would be
15 considered what your A1C number actually is. So,
16 I would think that this would be a parallel. The
17 process would be was your hematocrit checked; the
18 outcome would be was your hematocrit low enough
19 that you, then, needed a transfusion.

20 MEMBER KLIGER: Then, the hematocrit
21 is the outcome, not the transfusion.

22 DR. MESSANA: Maybe I should make my

1 opening statement that attempts to associate or
2 demonstrate that achieved hemoglobin or the
3 process of anemia management by a dialysis
4 facility, those are processes and intermediate
5 outcomes or intermediate outcomes and processes,
6 respectively, that are strongly associated with
7 subsequent transfusion risks in this population.

8 MEMBER KLIGER: I would buy that, but
9 the transfusion rate itself is a process. The
10 intermediate outcome, indeed, would be the
11 measures of adequacy of anemia management.

12 DR. MESSANA: So, I'm certainly not,
13 based on the discussion from last year, and the
14 fact that what argument you can make when you
15 submit to NQF, I mean, I would beg for a little
16 bit of consistency here. Last year we moved
17 forward after this back and forth and talked
18 about this as an outcome. I prepared this
19 measure this year as an outcome measure,
20 describing in the evidence links how the
21 intermediate outcomes and processes related to
22 the transfusion events. And I would just beg for

1 some consistency in how we define this moving
2 forward.

3 CO-CHAIR CROOKS: Well, I hear what
4 you are saying. You got the impression from this
5 Committee within a year ago that, about a year
6 ago, that this should be brought back or
7 continued as an outcome measure. Now you're
8 hearing some discussion about that.

9 One way to proceed would be to go
10 through the process and, if someone on the
11 Committee says, "I can't vote for this because it
12 is not an outcome measure," that would be their
13 change to vote no. I don't know, is that another
14 suggestion how to --

15 MEMBER KLIGER: Yes, I am surely not
16 going to stand in the way of this for sure. I
17 mean, I might be in a small minority here.

18 CO-CHAIR ANDERSON: So, Frank, you had
19 your --

20 MEMBER MADDUX: Yes, I have a question
21 for Andrew, and it is just the question about
22 whether an outcome has to be knowable by the

1 target responsible party. In this case, there
2 are substantial questions about whether this
3 outcome might even be knowable by the facilities
4 as the object of the measure, as compared to
5 hospitalization where the patient doesn't show up
6 and where you can ask them when they come back.
7 This is one that is a little tougher for me.

8 MR. LYZENGA: In the sense of whether
9 or not a transfusion is an identified event?

10 MEMBER MADDUX: Whether today
11 transfusion is an identifiable event by the
12 target of the measure, which is the facility.

13 MR. LYZENGA: I think that would be
14 something that would come up in a validity
15 discussion most likely.

16 MEMBER MADDUX: Yes, I think
17 feasibility.

18 MR. LYZENGA: Yes, but I don't know
19 that it is necessarily applicable to this
20 question of the type of measure it is. I think
21 that would apply also to any kind of measure, a
22 process or an intermediate outcome, whether the

1 definitions are precise and unambiguous enough
2 and knowable, that they can be collected reliably
3 and reflect on the performance of a facility or
4 the accountable entity, if that makes sense.

5 MEMBER MADDUX: So, I guess the answer
6 to the question would be that, for an outcome
7 measure, there isn't a requirement that the
8 accountable party necessarily know of the
9 outcome?

10 MR. LYZENGA: I think, again, that may
11 be something that would come up under validity,
12 whether that is -- I don't know, I would ask,
13 Sarah, do you have any thoughts on that?

14 MS. SAMPSEL: Yes, I mean, going back
15 to your question, that is not how we have it
16 defined as a requirement. I mean, it is an
17 interesting question and it is something that
18 comes into play, but that one is hard.

19 MR. LYZENGA: I'm sorry about that
20 question.

21 MS. SAMPSEL: I'm sorry, what?

22 MEMBER LATTS: For hospitalization as

1 an outcome measure, the accountable party, you
2 know, wouldn't necessarily know if someone was
3 hospitalized somewhere else.

4 MEMBER MADDUX: Well, they would know;
5 they don't show up. In this case, the patient is
6 going to keep showing up. While I play the
7 "not," something will have happened in between
8 you could ask them about, and they might report
9 that. But, just as likely, they might not
10 recognize what you're asking or have some other
11 mechanism to know.

12 And so, my question is about
13 transfusion, but it is really more about whether
14 an outcome measure has to be knowable by the
15 accountable party.

16 MS. SAMPSEL: I don't think so.

17 The other thing I just wanted to
18 mention, and Andrew has talked about this a
19 little bit, where this whole interpretation of
20 outcome versus process, intermediate outcome, it
21 comes through the interpretation of the evidence
22 criteria. The rest of the criteria, of course,

1 are going to vote the same.

2 So, really, what we would like to get
3 from you before we go to any kind of a vote isn't
4 an outcome or process, but is there evidence that
5 supports the fact that, you know, the rationale
6 for this measure that I guess reducing or
7 assessing this ratio of the transfusion rate is
8 linked to evidence of better outcomes.

9 CO-CHAIR CROOKS: Well, that is a bit
10 different. If it is an outcome, then the
11 evidence challenge is to show that there is a
12 process that affects this outcome as opposed to
13 sort of an opposite. It is not that this outcome
14 affects something further down. It is what makes
15 this outcome better, right?

16 MEMBER FISCHER: Can I make a
17 suggestion? I mean, I think it would be nice to
18 hear from the developer. So, myself and Lisa and
19 Jessie reviewed this, and I had corresponded
20 about this point via email with Andrew. I know I
21 did, and I believe Lisa and Jessie did as well,
22 that I evaluated the evidence, treating it as an

1 outcome measure, notwithstanding the concerns
2 that everyone has nicely articulated.

3 And I think a lot of these points will
4 come and we will get to the evidence. We'll have
5 a discussion and, then, we will have a vote, just
6 for the sake of kind of continuing to move
7 forward.

8 CO-CHAIR CROOKS: Josh has been
9 waiting for a while to make a comment.

10 MEMBER ZARITSKY: No, no, it is
11 exactly what Michael said.

12 CO-CHAIR CROOKS: The same comment?

13 MEMBER ZARITSKY: I mean, I said,
14 listen, if you want to consider it, I am fine
15 considering this as an outcome. Let's just
16 evaluate the evidence, then, based on an outcome
17 and saying this is a surrogate marker for an
18 outcome. If the evidence is not there, then we
19 have got a problem. But we are just going to
20 look at the evidence different than consider it a
21 process as we did before, what Michael said.

22 CO-CHAIR CROOKS: All right. So,

1 would you continue then, please?

2 DR. MESSANA: Okay, great.

3 So, I am glad the opening comments
4 have gone so smoothly.

5 (Laughter.)

6 The last point that I will make, just
7 for the sake of time, there has been much
8 discussion about variation in transfusion billing
9 and documentation in Medicare claims both here
10 and in public comments over the last year.

11 The fact is, at the dialysis facility
12 level, this transfusion measure, the one that is
13 being presented here, as compared to the one
14 presented last year which uses somewhat different
15 definition for a transfusion of that for Medicare
16 claims, is pretty insensitive to changes in the
17 definition of a transfusion of that, whether one
18 excludes a certain subcategory of codes versus
19 another.

20 Using objective criteria, about 95
21 percent of facilities have the same
22 classification for their STRR under the two

1 alternative definitions of transfusion. That is
2 the so-called more restrictive or conservative
3 version presented here and the broader definition
4 that was used last year.

5 For the 4 or 5 percent of facilities
6 that change classification based on how the
7 transfusion events were identified from claims,
8 all the changes occurred across one category.
9 So, nobody jumped from flagging as worse than
10 expected to better than expected. All the
11 changes were across one boundary. So, worse than
12 expected, as expected, or as expected or worse.

13 And so, given the small impact of the
14 definition of transfusion, that became a big
15 discussion last year. I really believe that the
16 important tradeoff that this group must consider
17 is the potential negative consequences to
18 dialysis patients associated with failure to
19 endorse this measure versus the potential
20 negative consequences of misclassifications for a
21 minority of dialysis facilities.

22 That's all. Thank you.

1 MEMBER FISCHER: I am going to follow
2 the script, first, just introducing the measure.
3 I think it has been stated. And then, just the
4 description, just so we are all on the same page.

5 This is an all-adult dialysis patients
6 to ratio of the number of eligible blood cell
7 transfusions observed in patients dialyzing at a
8 facility to the number of eligible transfusion
9 events that would be expected under a national
10 norm after accounting for patient characteristics
11 within each given facility.

12 Eligible transfusions are those that
13 do not have any claims pertaining to the
14 comorbidities, which we will get to later under
15 the specifications. The idea is better quality
16 is a lower score.

17 This is a facility-level measure.
18 This was discussed last time. I will come up to
19 some of the points of discussion. One of them we
20 touched upon, whether it is an outcome measure,
21 but I treated this as an outcome measure and as a
22 new measure since it is here for the first time

1 and it has not been endorsed previously.

2 I think the first thing to drop down
3 to, just kind of following the script, is to
4 discuss evidence. One of the questions posed
5 under outcome measures is, are there processes of
6 care that can influence this outcome? And I felt
7 that it was yes. Specifically, use of ESAs and
8 IV iron are processes that affect this outcome.

9 In terms of the evidence itself, there
10 were 25 citations of evidence that were provided.
11 Much of it is derived from observational studies
12 and much of it is derived about efficacy of ESAs
13 and factors predictive of what leads to a
14 transfusion.

15 In terms of kind of very robust
16 evidence about transfusions and other more
17 routinizable outcomes, a lot of that or the one
18 important study I think that presented was
19 looking at how transfusion leads to subsequent
20 decreased rate of kidney transplantations and
21 worse kidney transplant outcomes.

22 And there was one recent article

1 presented that showed a strong relationship
2 between blood transfusions, PRA, and subsequent
3 worst graft outcomes. Now there were other
4 adverse effects with blood transfusion that were
5 discussed, but there is not evidence for. But
6 these include, and well-known to many people on
7 the Committee, reactions, infections,
8 compromising future vascular access, and cost.
9 And those may not be a dispute, but I am just
10 going -- those weren't supported by the 25 pieces
11 of evidence.

12 The other, I think, study that was
13 interesting was one that is in press by Maloney
14 that looked at 400,000 hemodialysis patients
15 between 2009 and 2012. What they did is they
16 were trying to look at how changes in the bundle
17 and safety around ESAs have impacted transfusion
18 and how does that subsequently impact outcomes of
19 care.

20 What they found, that at facilities
21 that had greater dose reductions and smaller dose
22 escalations, NESAs had lower hemoglobin values

1 and higher transfusion rates. I don't think
2 there is any surprise there. Conversely,
3 patients at facilities that had greater dose
4 escalations and larger small dose reduction had
5 higher hemoglobin levels and lower transfusion
6 rates.

7 Importantly, there were no clinically-
8 meaningful differences on all-cause or cause-
9 specific hospitalization events across these
10 groups. That varied by ESA use and subsequent
11 transfusion use. And I only bring this up
12 because, other than the kidney transplant,
13 relating this to another recognizable outcome,
14 there wasn't a lot of data for that.

15 I think the other source is always
16 expert opinion. I think we have to take that,
17 obviously, into account. And our own Dr. Klinger
18 wrote a commentary on KDIGO in 2012. He spoke
19 about there is a lack of research supporting
20 optimal transfusion strategy for ESRD patients,
21 and it is difficult to weigh the risks and
22 benefits of red blood cell transfusion, I thought

1 was one of the pithy points from that opinion
2 piece.

3 And then, the last thing I will say --
4 well, two more things and, then, I will be quiet
5 -- there is a 2014 AJKD article that really
6 reported a proof of concept at developing such a
7 measure of standardized transfusions. I think
8 they really made the point that this might be a
9 more meaningful way of having a quality measure
10 around the domain of anemia than what we have had
11 before. And we will get into that later, about
12 what was in the QIP and what isn't anymore.

13 And then, lastly, there was a
14 Technical Expert Panel meeting hosted by the
15 Arbor Research Collaborative for Health in 2012
16 that strongly recommended a measure such as this.
17 I don't have any further details of the meeting
18 or the details thereof, but that is the summary
19 of the evidence as was presented in the
20 application.

21 I don't know if the developer has
22 anything further to add. And then, I will let

1 Jessie and Lisa, if they have any additional
2 comments.

3 DR. MESSANA: The only addition -- I
4 think that is a great summary; thank you, Dr.
5 Fischer -- but the only addition, there was a
6 patient-level retrospective observational study
7 and, then, a facility-level similar-design study
8 from the Chronic Disease Research Group in '13
9 and '14, I think, or it might have been '12 and
10 '14, that are listed as well that show
11 association of achieved hemoglobin in dialysis
12 facilities predictive of subsequent transfusion
13 risk.

14 So, that is all, but I agree with the
15 summary.

16 MEMBER LATTS: The only thing I would
17 add, and this may be better under the validity
18 section, but I think it is very important that,
19 as we are considering policy decisions on a
20 global basis, that we consider measuring the
21 implications of those changes. And so, I think
22 that having the ability to measure those, the

1 implications of various policy decisions, is a
2 critical feedback loop. We can argue about
3 whether or not this is the perfect measure, but I
4 think, conceptually, we need to be able to do
5 that as it feeds into the evidence.

6 MEMBER HARTWELL: This is Lori
7 Hartwell. I would just like to speak.

8 I think, too, that there may be some
9 issues with this measure, but it is very
10 important to patients. We don't have anything to
11 measure anemia anymore in the country due to the
12 lack of the FDA guidance. I think this is a real
13 marker of anemia treatment in the country and if
14 patients have to get a blood transfusion as a
15 result of it.

16 With regard to the high antibody
17 level, I mean, it is known to the people in the
18 group that it is harder to get a transplant.
19 Even UNOS recognized this by giving you extra
20 points to go to the top of the list. So,
21 therefore, I would just like the Committee to
22 consider that.

1 CO-CHAIR ANDERSON: Alan?

2 MEMBER KLIGER: Michael, can I ask you
3 and the others that did this more thorough review
4 perhaps than some of us did of the evidence? It
5 sounds from your description, and from my reading
6 of this, that the evidence really is in two
7 areas. One is in patients who are candidates for
8 kidney transplantation, and the second is in
9 patients who are on ESAs and where the ESAs are
10 manipulated to either be less, or whatever, and
11 the relationship to transfusions.

12 My question is, is that a correct
13 interpretation? And the reason I ask your
14 opinion about that is because this measure isn't
15 particularly directed at specifically either of
16 those subpopulations, but is directed against all
17 patients.

18 MEMBER FISCHER: I think that, yes, I
19 would agree. But, again, I think that there was
20 expert opinion presented from a TEP and opinion
21 pieces, expert opinion that they cited in journal
22 articles. We have to weigh that as evidence, the

1 empirical evidence.

2 To me, the strongest was in regard to
3 kidney-transplant-eligible patients. And just
4 talking aloud, then one could think, is this
5 something where you want to be targeting that
6 subgroup where there is the most evidence? I
7 think it is philosophical about kind of what
8 level of evidence that one believes is needed to
9 achieve that.

10 But, in terms of robustness, I found
11 it most convincing in terms of negative
12 downstream implications for a kidney transplant.
13 I don't know, Lisa and Jessie, if you had a
14 different impression.

15 MEMBER LATTS: I agree with that. The
16 only thing I would add is that I think, even
17 though small, the evidence of infection with
18 transfusion is a real thing that doesn't
19 necessarily need to be proved here.

20 MEMBER FISCHER: I think, again, that
21 is why I say there is expert opinion and those
22 things have been articulated along with other

1 concerns. I am presenting what was in the
2 application, the data as is, summarizing it and
3 trying to be in an unbiased fashion, but distill
4 it down in a way that the pithy details I think
5 are apparent to all to inform a voting decision.

6 CO-CHAIR ANDERSON: Josh? Who? Yes,
7 Josh, yes. Oh, sorry. Okay. Ishir?

8 MEMBER BHAN: I guess I am still
9 struck a little by this issue of what are the
10 downstream effects. Certainly, I think the
11 transplant effect is probably a real thing to
12 consider, although, as pointed out, it may be not
13 applicable to everyone.

14 And certainly there are concerns about
15 infection, although those concerns may also be
16 there with alternative treatments. So, iron,
17 being aggressive about iron repletion may have
18 similar effects; also, potential effects on the
19 vasculature.

20 And then, as well, we know, and I
21 think it has become increasingly recognized over
22 the past few years, the effects of excess in ESA

1 use. So, I think we have to look at this in that
2 context.

3 I think Peter pointed this out in the
4 beginning. Are we sure that this is a bad
5 outcome? You know, I think you could make
6 arguments about good deaths and bad deaths and
7 things. But, generally speaking, we would like
8 to reduce the mortality. And I am not so sure
9 that is quite so clear with regard to
10 transfusion.

11 CO-CHAIR CROOKS: The other downstream
12 effect that does affect the patient usually is
13 cost. If we give the right amount of
14 transfusions and not excessive, then I believe
15 that is less expensive than giving ESA. And that
16 may, in fact, be a motivation -- I don't know --
17 for CMS to develop this.

18 Alan?

19 MEMBER KLIGER: But, Peter, I would
20 argue that you don't know what the right number
21 of transfusions are. That is the flaw in that
22 type of an argument.

1 CO-CHAIR CROOKS: Okay.

2 MEMBER FISCHER: The last thing I will
3 just say, it is worth referring back to the
4 algorithm that NQF has, right? And I think if we
5 start in box one and we agree that this is a
6 health outcome as submitted -- and I think there
7 has been discussion now over the last 12 months
8 about that -- then you move to box two. And
9 really, that asks you simply, do you agree that
10 the relationship between the measured health
11 outcome and at least one healthcare action is
12 identified and supported by this stated
13 rationale? I mean, this is the algorithm NQF
14 has. I guess, to me, the answer is yes, because
15 there are clearly actions that we do, as I
16 articulated earlier, that are obvious to all that
17 impact this outcome.

18 Again, I reviewed this after
19 conversations offline earlier with Andrew and
20 others, that I believe this is an outcome measure
21 as submitted.

22 MEMBER GREENSTEIN: I just want to

1 point one thing out. We are going to translate
2 on sensitization. Probably what is happening now
3 is that what is increasing sensitization rates is
4 the fact that you have had a previous transplant
5 more than blood transfusions. And that is really
6 what is going on.

7 DR. MESSANA: So, Dr. Greenstein, I
8 believe that is correct, although I think that
9 the article that was referenced suggests that
10 there is synergism between the other sensitizing
11 events and blood transfusion.

12 And in response to the argument that
13 we don't know what is the most effective anemia
14 management therapy, I would argue that I know
15 what fraction of patients on chronic dialysis in
16 the United States are on EPO. The standard of
17 care in this country is transfusion avoidance for
18 the vast majority of our patients using EPO. It
19 is in the package insert and we are all using it
20 in the vast majority of our patients. For any
21 individual patient, the risk/benefit is
22 uncertain, I would agree, but I think the

1 standard of care is transfusion avoidance by use
2 of ESAs and other appropriate agents.

3 CO-CHAIR CROOKS: Franklin was first.

4 MEMBER MADDUX: I just have a
5 question, Joe, and I don't know the answer to
6 this. There have been drastic changes in
7 transfusion policies around cardiac surgery and
8 other areas of medicine, hospital medicine, and
9 so forth. What is the data with regard to what
10 appropriate transfusion policies might there be
11 for end-stage renal disease?

12 DR. MESSANA: I suspect you probably
13 have an inkling about the answer, having written
14 in that area as well. I have run across some of
15 your blood-saving literature.

16 However, most transfusions occur in
17 the inpatient setting, and I believe that the
18 decisionmaking around most of those transfusion
19 events is probably covered by the American Red
20 Cross and other consensus organization
21 statements, since most of these transfusion
22 events occur in the hospital.

1 I think that a fair statement about
2 consensus is that, if the hemoglobin is less than
3 seven, there is very little argument about
4 transfusing it. If it is between seven and ten,
5 it is situational. If it is over ten, there is
6 little or no justification for transfusion. That
7 would be my brief summary of what I am able to
8 find from Red Cross and international consensus
9 statements. So, my guess is that ESRD patients
10 fall under that rubric.

11 CO-CHAIR CROOKS: Josh? And then, I
12 wanted to try to get to voting.

13 MEMBER ZARITSKY: Just briefly to
14 reiterate, I mean, the problem I have, if we are
15 going to use it as an outcome, and the evidence
16 is that, as time has changed, we have to come to
17 recognize that, sure, we wanted to avoid
18 transfusions because we had EPOGEN. But now we
19 have come to recognize that, like you said,
20 EPOGEN carries a black box. These patients that
21 we drive for very high hematic -- it is not
22 necessarily the ones that can achieve it -- they

1 do worse. And so, the question is, where does
2 transfusion play a role in these patients? And I
3 don't think we have an answer.

4 We clearly see that transfusion can
5 sensitize a patient, but I'm just not so certain
6 about whether transfusion in the setting of
7 patients who are resistant to EPO is a bad thing
8 or a good thing. I don't know. That is where I
9 am as far as looking at the evidence.

10 CO-CHAIR CROOKS: So, if we are to
11 treat this as an outcome measure, then our vote
12 is to the point of, is there anything in the
13 process of care that will affect this outcome?
14 And that seems pretty straightforward.

15 If we were to vote on it as a process
16 measure, then all these other issues we have been
17 talking about, that transfusing has negative
18 outcomes or is against FDA, the black box warning
19 or other things.

20 If it is an outcome measure, the task
21 for the developer is to show that there is at
22 least one process of care that affects this

1 outcome, and that's it. If it is a process
2 measure or intermediate outcome, then the burden
3 is to show that improving that process or
4 improving that intermediate outcome affects
5 health outcomes further down the line. If they
6 could show both of that, then it doesn't matter
7 maybe whether it is an outcome or process
8 measure.

9 And I don't know that we are at that
10 point, but we need to vote and we need to know
11 why we are voting and what we are voting for, I
12 think. So, I think we should vote on it as an
13 outcome measure, and in that case the burden is
14 that there is at least one process of care that
15 can affect this outcome.

16 Any other discussion or would you like
17 to put up a different rationale? No? Okay.

18 So, let's vote on it. Does it meet
19 the evidence criteria as an outcome measure?

20 MS. OGUNGBEMI: We are now voting on
21 Measure 2979, Standardized Transfusion Ratio for
22 Dialysis Facilities. We are voting on evidence

1 for health outcome measure. Your options are 1,
2 yes, and 2, no. Voting is open.

3 (Voting.)

4 The results are 90 percent yes and 10
5 percent no. Measure 2979 passes on evidence.

6 MEMBER FISCHER: I will just continue,
7 then, to follow the script. The next part is
8 opportunity for improvement. If you can, keep
9 scrolling down.

10 What they have showed -- and this is
11 shown in detail in the worksheet -- is data on
12 performance gap across facilities. And this was
13 based on CROWNweb and Medicare claims data. As
14 we will get into, the Medicare claims data is
15 what is used to capture transfusion events, both
16 inpatient and outpatient.

17 And they show standardized transfusion
18 ratios, STRs, for 6,000 facilities from 2011 to
19 2014. And you can look that -- I mean, they
20 present means with standard errors, and they also
21 present it by percentiles. There isn't
22 substantial changes over time, and there is a

1 large spread in the data -- that was my
2 impression of that -- showing that there is quite
3 a bit of variability. And it would seem to
4 corroborate or suggest that there is a
5 performance gap.

6 The one thing I would just say is,
7 then, later on, when they talked about it -- and
8 I don't want to go out of order, but I think this
9 is relevant -- when they talk about the SCS, the
10 sociodemographics, this I think has a little bit
11 more maybe tangible clinical interpretation,
12 where they, similar to the standard
13 hospitalization ratio, the real question is that,
14 using this STR which is based on a national
15 average and, then, adjusted for case mix at a
16 given facility, classifying facilities as better,
17 no different, or worse than this national
18 standard, and they calculated these scores like
19 is done with SHRs using generalized estimating
20 equations, which kind of gives you a sense as to
21 how does that bear out in terms of significance.

22 And this is shown kind of much later

1 on in the worksheet. But I thought what was
2 interesting is that this has a slightly different
3 message, I would argue, than what we see kind of
4 posted up there, in that, when all is said and
5 done, 93 percent of the facilities come out to be
6 as expected or better, which only 6 percent are
7 worse.

8 And I think, then, again, this is
9 philosophical, whether one views that still as a
10 performance gap. I guess I want to be careful
11 that this is not measure up for maintenance. So,
12 this may not be as critical as a measure we are
13 considering for re-endorsement. But I did want
14 to bring it up, and if I have misinterpreted the
15 data, the developers can correct me. But I
16 thought it was important to talk about that just
17 in terms of it looks like 6-7 percent of
18 facilities are actually worse than what they
19 would expect.

20 CO-CHAIR CROOKS: Yes, and while you
21 are answering the question, could you just
22 briefly explain where the better than expected,

1 as expected, and less than expected, how that is
2 actually determined?

3 DR. MESSANA: Right. So, the flagging
4 analyses are maybe drifting towards operational.
5 The Efron empiric null approach with z-scores was
6 used, so that we could control the flagging. So,
7 it was actually set up with the anticipation that
8 5 percent of facilities expected would be on
9 either tail.

10 So, it is kind of you can be as
11 sensitive and lose specificity if you want. We
12 set it up that way intentionally. I'm not sure
13 it is appropriate critique necessarily to say
14 that it can't be an impactful measure based on
15 the relatively-strict criteria we used.

16 MEMBER LATTS: And the only thing I
17 would add, then, is from a performance gap
18 perspective, you know, again, given the changes
19 in reimbursement, this would be one that you
20 would necessarily would want to follow moving
21 forward to see if the gap changed moving forward.

22 CO-CHAIR CROOKS: Okay. More

1 discussion about the performance gap?

2 MEMBER ZARITSKY: So, if I understand
3 right, there is always going to be -- you set it
4 up so that there is 5 percent -- there will
5 always be 5 percent?

6 DR. MESSANA: I think that drifts into
7 CMS policy decisions. We set it up to mirror
8 standardized hospitalization using a similar
9 technique, reasoning that a small fraction in
10 either tail would be appropriate.

11 And how that might be used in a
12 different program, right, is certainly beyond my
13 ability to speak. It is set up for the purposes
14 of consideration here with being relatively
15 specific to extreme outlier facilities.

16 MEMBER KLIGER: So, I guess, Josh, it
17 gets back to my basic concern, that there is ever
18 a distribution, there are surely going to be
19 outliers. By definition, we have set it up. And
20 if we imply that that means that on one or the
21 other end that people are getting inappropriate
22 care, I don't see the evidence that that is the

1 case here. And so, when you look for performance
2 gap, I find it hard to separate that decision
3 from the underlying issue around transfusion.

4 CO-CHAIR CROOKS: Okay. Other
5 comments on the performance gap?

6 (No response.)

7 Okay. I think we are ready to vote on
8 that.

9 MS. OGUNGBEMI: We are now voting on
10 performance gap for Measure 2979. Your options
11 are 1, high; 2, moderate; 3, low, and 4,
12 insufficient. Voting is open.

13 (Voting.)

14 We're waiting on one more vote. Could
15 everyone just please vote one more time? Thank
16 you.

17 (Voting.)

18 Results are in, and on performance gap
19 we have results of 10 percent high, 60 percent
20 moderate, 25 percent low, and 5 percent
21 insufficient. Measure 2979 passes on performance
22 gap.

1 CO-CHAIR CROOKS: Okay. The next
2 issue is reliability and specifications.

3 Yes, Michael.

4 MEMBER FISCHER: So, let me just kind
5 of go back through the numerator. Again, it is a
6 number of eligible observed RBC transfusion
7 events. And this is both capturing inpatient and
8 outpatient transfusion events.

9 The denominator -- and I won't reread
10 the whole thing -- but denominator was number of
11 eligible red blood cell transfusion events at the
12 expected facility given the patient mix. The
13 exclusions, which I don't think we have talked
14 about, now I think is the opportunity to do that
15 -- we can do that here; I think it also has
16 relevance to validity -- include transplant
17 hospitalizations, cancer, bone marrow problems,
18 and sick cell disease within one year of
19 observation.

20 And they go into some detail about why
21 they look back one year. They performed a
22 logistic regression model demonstrating -- and

1 they didn't put the results, but they just kind
2 of made a statement, which I assume summarizes
3 their findings, that when they looked back longer
4 periods of time, it didn't substantially lead to
5 a different set of exclusions. So, I think that
6 is why they are doing one year.

7 They also provide a detailed figure
8 giving a case example. I think it nicely looks
9 at how, when the exclusion is captured and, then,
10 how it would be a forbidding period for one year.
11 I think it illustrates, because I think it is a
12 little bit hard sometimes to envision, when you
13 are thinking of exclusions during a time period,
14 but it nicely, I think, kind of characterizes how
15 that would be done.

16 The data sources I think, because it
17 gets into some of this, they plan to use for
18 transfusion events -- this comes from Medicare
19 claims ICD-9 and Value Center codes. Outpatient,
20 they are HCPCS and Revenue Center codes and,
21 then, CROWNWeb data for a lot of the other
22 elements that we require to calculate it.

1 I thought the data elements were
2 clearly-defined. The codes were provided. I
3 thought things seemed logical and clear.

4 One thing that I think is always
5 interesting is in terms of the things that go
6 into the expected value calculation. I think it
7 is kind of the customary covariates that they use
8 for SHR ranging from calendar year to diabetes to
9 age. I think we can take that as we have for
10 other measures that have been endorsed.

11 The one thing that I did have a
12 concern was, just kind of hypothetically
13 thinking, what about individuals -- and I am now
14 thinking about inpatients -- who have trauma or
15 some unexpected surgery, blood loss, require
16 transfusions? And that, you know, if you are
17 thinking about this measure, unless I have a
18 misunderstanding, that is not covered by
19 exclusions. That would be a negative attribution
20 to a facility in terms of the way the measure is
21 interpreted.

22 That was the one thing that, you know,

1 just how often does that happen, I don't know,
2 but I think it is one of those things where,
3 really, is that a reflection of quality of care
4 at the dialysis facility when people have acute
5 hospitalizations for non-dialysis-related reasons
6 that entail acute blood loss requiring emergent
7 transfusion?

8 I don't know if the developer has a
9 response. Or maybe I have misunderstood perhaps,
10 but that was one concern; there may be others
11 that Lisa or Jessie have about specifications.

12 DR. MESSANA: Thank you.

13 Michael, I think it is reasonable. We
14 presented this measure last year, unsuccessfully,
15 as being one in which there is shared attribution
16 for events. And I will provide one single
17 anecdote to describe what the literature says,
18 and some of that literature is in the 25 articles
19 that we have cited in the linking evidence.

20 I recently had a patient admitted to
21 the hospital for urgent four vessel coronary
22 artery bypass grafting. Diabetes was his cause

1 of end-stage renal disease. His hemoglobin at
2 his last visit with me was about 11.2 or 11.3
3 grams per deciliter before his admission to the
4 hospital. His post-operative hemoglobin nadired
5 at 7.2. Clearly, he had blood loss as a
6 consequence of surgery and potentially volume
7 overload, dilution, and whatnot, post-
8 operatively.

9 Had he entered the hospital, all other
10 events being the same, had he entered the
11 hospital with a hemoglobin of 9, both the
12 literature says and my clinical experience says
13 he would have gotten blood transfusion. Now was
14 the dialysis management the sole cause of the
15 potential exposure to ELO transfusion? No. But
16 we considered this a shared risk kind of
17 proposition, and that is explicitly what the TEP
18 discussed when we were developing the measure in
19 2012 under their guidance.

20 MEMBER FISCHER: I guess, I don't
21 know, maybe I shouldn't be drawing a distinction,
22 but I understand that. It is a good example.

1 But I am thinking of something that directly
2 contributes. I mean, if someone comes in with
3 acute GI bleed or some traumatic accident, it is
4 a little bit more difficult for me, again, just
5 thinking about how that, since that is going to
6 very linearly lead to a transfusion event. And
7 frankly, it could be independent of where your
8 hemoglobin was to start with, given the linearity
9 with that impact and hemoglobin, but maybe I am
10 splitting hairs as to how that would be saying
11 that is reasonable to include.

12 CO-CHAIR CROOKS: Lorian?

13 MEMBER DALRYMPLE: I actually agree
14 and made notes with similar -- it does seem like
15 there are certain events that should be excluded
16 such as acute GI bleed requiring hospitalization
17 when it is the principal diagnosis and our
18 patients are at heightened risk for GI bleed.
19 Even with old heparin, there's a number of
20 factors that contribute to it.

21 Another one I thought would be
22 reasonable to consider but much rarer, to be

1 honest, so not quite as important, are things
2 like polytrauma. Clearly, there are situations
3 where your dialysis facility care will have
4 minimal impact on whether you get transfused in
5 that setting.

6 But GI bleed, have you all looked at
7 this at all? Is it as frequent as we are worried
8 about or perhaps you examine this in sensitivity
9 analyses and it doesn't really play out as being
10 terribly relevant?

11 DR. MESSANA: I will I could say that
12 the latter was true, but most of the work that we
13 have done related to the prospective payment
14 system and looking at cost of EPO and recent GI
15 bleed is associated with increased EPO use and,
16 presumptively, greater risk for blood loss and
17 transfusion.

18 The reason it is specifically excluded
19 here is the TEP did not agree with you,
20 basically. The TEP believed that GI bleeding was
21 potentially influenceable, could be the result of
22 care by the dialysis facility in some situations,

1 and they did not want that included in the list,
2 and we stayed true to their recommendations.

3 CO-CHAIR ANDERSON: John?

4 MEMBER WAGNER: I just want to echo
5 the comments about GI bleeding. In my own
6 experience, that has been a problematic area for
7 care of our patients, not only acute, but
8 patients with recurrent GI bleeding, despite what
9 we considered to be optimal management, as well
10 as patients with inflammatory conditions,
11 autoimmune disorders, sometimes requiring ongoing
12 glucocorticoid therapy, associated at the same
13 time with other blood-loss anemia. So, we had
14 gynecological sources of blood loss as well as GI
15 sources of blood loss in such patients. Despite
16 our attempts to manage them with ESAs, it was not
17 sufficient.

18 CO-CHAIR ANDERSON: Frank?

19 MEMBER MADDUX: Yes, I am just
20 wondering if your analyses were able to
21 distinguish between patients that were out
22 patients at the origin of the transfusion order

1 versus hospitalized at the transfusion order, to
2 try to get a little bit at Lorian's question on
3 is there an acute issue that occurred, knowing
4 that most transfusions are happening in the
5 hospital, but they may be happening in the
6 outpatient department of the hospital or some
7 other site that wasn't associated with an
8 admission.

9 DR. MESSANA: Yes, I don't have the
10 answer to that. I think it would be asking a lot
11 of claims because there is this ascertainment
12 bias, right? People get admitted because you are
13 more likely to identify diagnoses that may have
14 preceded hospitalization because the admission is
15 often associated with reporting of a significant
16 increased number of claims. So, I don't think I
17 can provide an answer. We clearly can
18 differentiate transfusion events that occur
19 inpatient and outpatient, but the timing of when
20 the clinical condition came up, using Medicare
21 claims I think is limited.

22 Also, the hemoglobin values that we

1 have access to generally, because of the
2 reporting, come from the prior month. And so,
3 they may be late in the month; they may be early
4 in the prior month, but they are from the prior
5 month, relying on the dialysis providers to get
6 those.

7 MEMBER SOMERS: I just wanted to
8 clarify whether this measure is supposed to
9 pertain to children. Because in the brief
10 description of the measure, it talks about this
11 being for adults, but children aren't excluded in
12 the denominator.

13 My concern would be, since a minority
14 of children have Medicare coverage, that the data
15 we would get for children would not really be
16 true in terms of reflecting transfusion ratios.
17 It wouldn't necessarily penalize. It would be
18 underestimating things because we wouldn't be
19 able to gather that data for the inpatients in
20 terms of transfusions that they may receive.

21 DR. MESSANA: Yes, so I am surprised
22 you bring that up because my belief was that this

1 was an adult measure, that this was intended to
2 be an adult measure. We have almost no data to
3 identify transfusion events because of the
4 relatively lower fraction of pediatric patients
5 that are Medicare and the small numbers. So, I
6 will have to go back and double-check that, but
7 my recollection was this was intended as an adult
8 measure.

9 CO-CHAIR ANDERSON: In your stage one
10 model, there are age groups for zero to 14, which
11 I think leads us to believe that children are
12 being included in the model. And there is also a
13 15-to-24-year-old age group.

14 DR. MESSANA: So, as I say, the exact
15 specifications that we are presenting, I will go
16 back and double-check on those. And Doug may
17 want to comment on the model, if you have the
18 moment.

19 DR. SCHAUBEL: Yes, just to follow up
20 on your comment about stage one versus stage two,
21 since stage one is getting the regression
22 coefficients, so the basis for the adjustment.

1 And the second part is calculating the
2 numerator and denominator, which is done
3 separately. So, the stage one could, in fact,
4 include children. That wouldn't be a problem for
5 stage two.

6 MEMBER GREENSTEIN: I guess the other
7 thing should be these patients are many times
8 vasculopaths and they are going to undergo bypass
9 operations besides cardiac operations, and they
10 are going to get transfusion many times because,
11 you know, vascular surgeons like to give blood.

12 DR. MESSANA: I won't comment on the
13 description of vascular surgeons' preferences.

14 (Laughter.)

15 However, again, our literature
16 suggests that in the general hospitalized
17 population and ICU population and in surgical
18 population, one of the strongest predictors of
19 perioperative transfusion is preoperative
20 hemoglobin.

21 CO-CHAIR CROOKS: Lorien, your card is
22 still up?

1 MEMBER DALRYMPLE: I do have a
2 question for the developers regarding the
3 numerator count, just for clarity, because this
4 seems similar to me to last year's measure. So,
5 I was hoping you could provide information as to
6 whether it is or is not.

7 My understanding is, if a hospital
8 submits bills with procedure codes, every
9 transfusion counts, versus if a hospital submits
10 claims using a value code, it is one event,
11 meaning hospital A transfuses 10 units. And
12 let's say that is over 10 days. That is 10
13 events attributed to that facility. Whereas,
14 hospital B bills with a revenue code, again
15 administers 10 units, but that gets counted as
16 one. Is that an incorrect understanding of this?
17 Can you clarify?

18 DR. MESSANA: Yes, it is a little bit
19 off and, actually, when I reviewed the transcript
20 of last year's discussion. So, let me just try
21 to reclarify.

22 So, according to the Claims Processing

1 Manual and the Red Cross Billing Guidelines, what
2 you need to report or submit for an inpatient
3 transfusion event is a revenue code, right, which
4 really relates to whether the blood was purchased
5 or whether it was donated and, then, how the
6 hospital bills for blood processing and things
7 like that, and whether they can use the
8 transfusion, the cost of the blood in their cost
9 report. It is related to that, to the purchase
10 of blood versus blood being donated.

11 So, that revenue code is supposed to
12 be required. In addition, a procedure code or a
13 value code, a designated procedure code, ICD-9 or
14 now ICD-10 procedure code, designating what type
15 of blood product or what type of product was
16 actually transfused, cryoprecipitate, platelets,
17 frozen red blood cells, packed red blood cells,
18 whole blood, et cetera.

19 So, last year the metric that we
20 presented included transfusion events that were
21 only identified by the presence of a revenue code
22 without a procedure code. And that turns out to

1 be about 34 percent, 35 percent, depending upon
2 the year of potential transfusion events.

3 It also turns out that, based on your
4 comments from last year, we went back and looked
5 at regional variation, network, state-level
6 variation, hospital-level variation. And there
7 was really quite a variation across providers in
8 terms of whether the majority of transfusion
9 events were billed under just a revenue code or,
10 I will say more appropriately, more consistent
11 with the Medicare claims processing, which is
12 revenue code and a procedure code. Okay?

13 You can also document by submitting
14 just a value code, but that is a very small
15 fraction. So, the vast majority of transfusion
16 events are either procedure code, ICD-9 procedure
17 code, now ICD-10 procedure code alone, or in
18 combination with a revenue center code. And
19 then, there are a minority, a sizable minority,
20 that are just revenue center codes.

21 There is a lot of variability in just
22 a revenue center code percentage across states.

1 For example, Rhode Island I think has 14 percent
2 of transfusion events that are just revenue
3 center code. Utah has 74 or 75 percent that are
4 just revenue center code.

5 And so, we were concerned about that
6 variability and billing, particularly in the
7 context of the comments you all made last year
8 about reliability. So, we looked at the more
9 restrictive definition. And what is interesting
10 is that there does not appear to be any
11 association between state-level dialysis facility
12 flagging, whether you use one or the other
13 definition. And the two definitions are
14 including those transfusion events that are
15 identified solely by revenue center code or
16 revenue code versus only including transfusion
17 events that have both a revenue code and a
18 procedure code or just a procedure code, which is
19 also a very small percent or something like that.

20 So, that is the real focus of the
21 definitional difference, Lorien, is really
22 whether or not you accept revenue code alone as

1 sufficient evidence for a transfusion event. You
2 see a lot of variability across regions and
3 states based on that practice at the hospital
4 level. It turns out, though, that the STRR is
5 insensitive or pretty insensitive to which
6 definition you use.

7 We chose to use the more restrictive
8 version for presentation here because it gets rid
9 of some of that regional billing variability
10 concern. It also reduces the number of
11 transfusion events we identify by about 34
12 percent. For me, that is a bigger concern than
13 the regional variability.

14 MEMBER DALRYMPLE: But can I clarify
15 that point about procedure codes versus value
16 codes? Because my understanding from this
17 sentence is we identify a transfusion event for
18 each transfusion procedure code with a
19 corresponding unique date listed on the inpatient
20 claim; thus, allowing determination of multiple
21 transfusion events on inpatient claims with
22 multiple ICD-9 procedure codes. However -- the

1 "however" is my part -- for inpatient claims with
2 value code 37, we count the single transfusion
3 event.

4 So, when I read that, what it sounds
5 like to me is, if a hospital chooses to use
6 procedure codes, multiple events are coded,
7 versus if they choose to use a value code, a
8 single event is counted. So, at least my initial
9 understanding of that, and similar guidance is
10 provided for the outpatient, where they compare
11 HCPCS to Revenue Center, which you guys describe
12 in detail and how the counting works. So, my
13 initial impression is still your claim type
14 somehow determines your numerator count, but I
15 suspect value codes are infrequent, so less than
16 5 percent.

17 DR. MESSANA: It's extremely
18 infrequent, right. Well, it is about 1 percent,
19 something like that.

20 MEMBER DALRYMPLE: Okay.

21 DR. MESSANA: So, in theory, you are
22 correct. In practice, it is not impactful at

1 all.

2 MEMBER DALRYMPLE: Okay.

3 DR. MESSANA: The real issue is
4 revenue versus procedure codes. In the
5 outpatient setting, providers are instructed only
6 to submit one claim per day, no matter how many
7 transfusion events. And in the outpatient
8 setting we are absolutely constrained by that
9 claims processing regulation. So, in the
10 outpatient event, it is correct; you present two
11 different HCPCS for two different transfusion
12 products, but one revenue code. We can only bill
13 for one event on a day, but we are constrained by
14 the regulations.

15 In the inpatient setting, if a patient
16 receives a unit of whole blood and two units of
17 frozen packed red blood cells, you can identify
18 the differences by the ICD-9 procedure codes, and
19 there is no restriction on submitting multiple
20 transfusion claims per day in the inpatient
21 setting. That is the difference between
22 inpatient and outpatient.

1 CO-CHAIR CROOKS: Okay. I would like
2 to try to move on to the reliability. That was
3 just the specifications that we have been talking
4 about so far.

5 MEMBER FISCHER: Yes. Right. No, I
6 think this is a good discussion because we are
7 touching upon some of the key issues. This was
8 one of them from last year that I think was a bit
9 contentious. So, it is good that everyone has an
10 opportunity to air out their concerns and
11 potential explanations.

12 So, the second part of what we are
13 going to vote on with reliability is the
14 reliability testing. They tested at the measure
15 level only, not data elements, which is fine.
16 And they used the interunit reliability measure,
17 which has been used for several of the other ones
18 we have reviewed here today.

19 Just to remind folks, this score can
20 range, the IUR can range from zero to one, zero
21 revealing that most of the variation of the
22 measure, in this case the STR between facilities

1 is random noise. The closer you are to one, the
2 more likely it is that it is a good
3 characterization of interdifferences between
4 facilities.

5 So, I think we can put up whatever we
6 can, but they had kind of a nice box that looked
7 at IURs from 2011 to 2014. They did it overall.
8 And the first thing I will say is the trends over
9 time, they were very stable. The overall value
10 is around .65 or so, which most would consider to
11 be moderate.

12 The only concern I had here -- and I
13 think the developers point this out -- is that
14 there is a consistent discrepancy between small,
15 medium, and large facilities. And they broke
16 them down based on less than 46, 47 to 78
17 patients, and over 79. And it nicely divided the
18 overall 6,000 or so into three groups, about 17-
19 16 hundred apiece.

20 And if you look, and we can just look
21 at 2014 data, the IUR for small facilities was
22 about 0.3; medium, 0.5, and, then, the largest

1 facilities was 0.78. The immediate
2 interpretation would appear to be that the IUR
3 seems to indicate a lot more noise with small
4 facilities. That is probably not a big surprise,
5 but I think since it informs our assessment of
6 reliability, and there are no exclusions for
7 small facilities that I'm aware of, I think it is
8 important just to take that into consideration.

9 I don't know if Lisa or Jessie have
10 any additional comments.

11 (No response.)

12 CO-CHAIR CROOKS: So, we will have to
13 be deciding whether that makes the reliability
14 unacceptable or not.

15 Are there other comments on
16 reliability?

17 I'm sorry. Michael?

18 MEMBER SOMERS: I think that this
19 would be more evidence for why children should be
20 excluded from this measure, since most pediatric
21 dialysis centers are quite small, since measure
22 wouldn't be very reliable for that population.

1 MEMBER FISCHER: The one thing I was
2 just going to say is just, again, sticking to
3 kind of this script and our guidance from NQF, if
4 you worked through the algorithm, I think it
5 really comes down to box No. 6. Based on the
6 testing presented, you have high certainty and
7 confidence, moderate certainty or confidence, or
8 low. And I think that that, obviously, is a
9 matter of people's interpretation of the data
10 presented.

11 For me, I think we should probably --
12 I had moderate certainty, but my bounds of
13 moderate may be broader than others.

14 DR. MESSANA: So, just for
15 clarification, our support people in the back are
16 yelling at me no children, no children.

17 (Laughter.)

18 So, they can confirm that this is an
19 adult-only measure.

20 CO-CHAIR CROOKS: Okay. Are we ready
21 to vote on specifications?

22 Oh, I'm sorry, Lorien.

1 MEMBER DALRYMPLE: Can I ask a
2 question of the Committee then, particularly for
3 the main reviewers? My understanding is 1900
4 units fall into the small facility size, less
5 than/equal to 46, and the IUR in that group is
6 .30. And another 1900 fall into the medium-sized
7 dialysis facility group, and the IUR for that
8 group is 0.50.

9 So, could the main reviewers clarify
10 for us? I know you gave us your opinion,
11 Michael, on how you went through the board, but
12 it is challenging for me with such a large number
13 of facilities having IURs of .5 and .30 to know
14 how to use the guidance.

15 And I don't know if the NQF staff can
16 weigh in on this. Okay, they are shaking their
17 head no.

18 So, I guess the Committee and the main
19 reviewers are left to give us some guidance. You
20 know, it would be one thing if it was 10
21 facilities, right? We would all move on.

22 MEMBER FISCHER: I bring this up

1 because I wanted this type of discussion to
2 gather people's opinions. I am not dogmatic
3 here.

4 The thing I tried to remind myself is
5 how many of the measures that we vote on don't
6 provide reliability by facility size. I mean, I
7 am kind of six one way, half a dozen the other.

8 But the developers presented this
9 data, which I thought was quite interesting.
10 But, you know, if we only had seen the overall
11 IUR of .6, there would be no discussion; we would
12 be moving right along.

13 So, when you are giving additional
14 details that aren't necessarily requested, and
15 then, they raise the concerns -- no, I mean, I
16 probably should stop talking. But, I mean, I
17 think it leads to some cognitive dissonance about
18 how to process and arrive at a conclusion.
19 Anyway, kind of thinking along those lines.

20 CO-CHAIR CROOKS: Well put. Okay.

21 MEMBER DALRYMPLE: Can I ask the
22 developers if the model at all accounts for

1 facility size or attempts to deal with this? I
2 don't know if perhaps in the expected part this
3 somehow gets handled. Can you guys help us with
4 that?

5 DR. SCHAUBEL: Yes, and it does not.
6 And that's something that you wouldn't want to
7 do, because if you did that, you would be
8 comparing facilities at the same size. And if
9 there are systematic differences between large
10 facilities and small facilities, you would be
11 washing that away. So, no, it doesn't; no, you
12 wouldn't want to.

13 DR. MESSANA: I will add that, if this
14 measure is used in public reporting and things
15 like that, there are limits in terms of what
16 facilities would be reported on based on size,
17 but that is at the extreme. That is certainly
18 not the entire 1900 in the lowest tertile.

19 CO-CHAIR CROOKS: Shall we vote?

20 MS. OGUNGBEMI: We are now voting on
21 reliability for Measure 2979. Your options are
22 1, high; 2, moderate; 3, low, and 4,

1 insufficient. Voting is open.

2 (Voting.)

3 The results are zero percent high, 75
4 percent moderate, 25 percent low, and zero
5 percent insufficient. Measure 2979 passes on
6 reliability.

7 CO-CHAIR CROOKS: Okay. Let's move on
8 to validity.

9 MEMBER FISCHER: Okay. So, moving
10 along kind along the script to validity, I think,
11 you know, the specifications I think they come up
12 both with reliability and validity. I think we
13 have brought forth some concerns about
14 specifications such as polytrauma, acute GI
15 bleed. I won't revisit those now.

16 Moving on to testing for validity,
17 they did this, again, at the score level only,
18 which is fine. What they did is they looked at
19 the associations with tertiles of the STR with
20 SHR and SMR, which are currently-endorsed quality
21 measures. And using Poisson models, they showed
22 that STR tertiles were significantly associated

1 with both SMR and SHR, that the relative risk for
2 death and hospitalization increased with higher
3 tertiles of STRs, as that numerical value became
4 greater.

5 The other thing I think we talk about
6 with validity testing is face validity. And they
7 also provided face validity, and there was a
8 statement from the developers that six out of the
9 six voting members of CMS's 2012 Technical Expert
10 Panel voted to recommend the development of a
11 facility-level standardized transfusion average.

12 When I read that, it is "recommended
13 the development of," which is a little bit
14 different than recommending this specific
15 measure. But I don't want to parse words, but
16 just being careful to make sure I had a proper
17 interpretation of what was in the application.

18 I think the other thing, but maybe I
19 want to pause here, that we will need to talk a
20 little bit about is the SDS factor analysis. But
21 I will stop, and I don't know if Lisa or Jessie
22 or others have things to add.

1 MEMBER LATTS: No, I think you got my
2 comments.

3 DR. MESSANA: Well, I would like to
4 clarify accuracy of the information presented, if
5 that is okay, Peter. So, the third tertile
6 analysis that was performed I think is very
7 important relative to our discussion of outcome.

8 So, we showed that if you looked at
9 facility-achieved hemoglobin tertiles and their
10 relationship with subsequent transfusion events,
11 we showed statistically-significant dose-type
12 effects relationship under the validation as
13 well.

14 MEMBER FISCHER: So, then, I think the
15 other thing is to talk about, right, the SDS
16 factor analysis, correct?

17 Again, I think, Andrew, when we had
18 our conversation, our meeting the other week,
19 this was a trial period. There was analysis that
20 was presented in great detail, and other factors
21 that were looked into were things such as sex,
22 race, Hispanic ethnicity, employment insurance,

1 and outcome -- and income. Excuse me.

2 And they have some very nice, detailed
3 tables. Kind of just summarizing, there were
4 certain factors like female sex, Hispanic
5 ethnicity, employment that did appear to have an
6 impact on this measure. But, in the end, as the
7 developers characterize, a very small percentage
8 of facilities would actually change categories.
9 And the three categories I spoke about earlier,
10 it was around 1.5 percent or so, and that was
11 from same to worse, same to better. So, there
12 were trends in either direction.

13 You know, I think they went on to say
14 about -- and I think it is kind of a
15 philosophical question -- about whether one makes
16 additional adjustments for these factors. As I
17 understood from the developer, they don't plan on
18 doing that.

19 And they kind of went on to make, you
20 know, they gave some explanation thereof, despite
21 finding that some of these are significant as to
22 why they chose not to do that. For example,

1 regarding employment insurance status, we believe
2 the association between transfusion events and
3 these factors represent disparities in access to
4 care. And therefore, we do not believe that they
5 are appropriate risk-adjusters for quality
6 measures.

7 And they talked about some area-level
8 measures as well that reflect socioeconomic
9 disadvantage. The one thing they didn't comment
10 on that I guess -- and maybe I overlooked it, and
11 Jessie and Lisa can fill me in -- is I get that,
12 but what about Hispanic ethnicity? Because that
13 is something that I think -- you know, is that
14 worth consideration in terms of being a case-mix
15 adjuster or not? I don't know what Jessie and
16 Lisa thought or others or the developer,
17 additional comments.

18 CO-CHAIR CROOKS: So, as it stands,
19 then, there is no adjustment for SDS built into
20 the model right now? Correct?

21 MEMBER FISCHER: Correct. That's
22 right.

1 CO-CHAIR CROOKS: Okay. Other
2 discussion regarding the validity?

3 (No response.)

4 Okay. I guess we are ready to vote
5 then.

6 I'm sorry. Lorien? Hold it up.

7 MEMBER DALRYMPLE: A question of
8 either other Committee members or the developers,
9 just to clarify the interpretation of the
10 standardized transfusion ratio. So, when I was
11 looking at the earlier data, it looks like raw
12 rates of transfusions have come down since 2012 a
13 little bit, but it kind of peaked in 2012. But
14 the standardized transfusion ratios and the
15 distributions did not look notably different to
16 me over the years. Is that a correct
17 interpretation or incorrect? And can you kind of
18 help us understand why the rates are coming down,
19 but the standardized transfusion ratios aren't
20 obviously coming down? So that we know how to
21 use it as a performance metric: am I getting
22 better kind of issue?

1 DR. MESSANA: It is analogous to the
2 SHR and SMR. They have year effects built into
3 the model. So, unless you tied it back to some
4 baseline year, the STR as developed is adjusted
5 or normalized to the national mean, median. Mean
6 or median are almost the same.

7 MEMBER DALRYMPLE: The expected are
8 getting better.

9 DR. MESSANA: The expected for that
10 year, yes.

11 MEMBER DALRYMPLE: So, the observed
12 relative to the expected is staying? Okay.

13 MEMBER FISCHER: The only other
14 question I had is I think in the SHR and SMR,
15 claims data for Medicare is now used to update
16 for prevalent comorbidities. After I reviewed
17 this, I looked at those, which I was not
18 primarily assigned to, but, then, I went back to
19 this. And I was wondering why that also isn't
20 true for this measure, why it wouldn't somewhere
21 be feasible since things such as diabetes and
22 others go into the determination of the expected

1 value. I just didn't know if the developers had
2 a comment.

3 DR. MESSANA: So, the TEP for this
4 metric was in 2012. The TEP for use of prevalent
5 comorbidities was in 2015, and you will be
6 talking about that later. The approach that was
7 recommended by the 2012 TEP was to use exclusion
8 as a risk-mediation approach as opposed to risk-
9 adjusting for a bunch of different comorbidities.

10 The 2015 TEP was asked specific
11 questions about whether prevalent comorbidities
12 specifically with regard to hospitalization and
13 mortality could be the result of facility
14 practices. We don't have specific information
15 about a Technical Expert Panel's opinions about
16 how comorbidities could be the result of facility
17 care that might influence the transfusion metric.

18 But our risk-abatement strategy
19 excludes 15 to 20 percent of Medicare patients
20 each year. So, we are using the all-or-none
21 risk-abatement approach.

22 CO-CHAIR CROOKS: Okay. Any other

1 discussion?

2 (No response.)

3 Let's vote.

4 MS. OGUNGBEMI: We are now voting on
5 validity for Measure 2979. Your options are 1,
6 high; 2, moderate; 3, low, and 4, insufficient.
7 Voting is open.

8 (Voting.)

9 Results are zero percent high, 75
10 percent moderate, 25 percent low, and zero
11 percent insufficient. Measure 2979 has passed on
12 validity.

13 MEMBER FISCHER: I think next up is
14 feasibility.

15 CO-CHAIR CROOKS: Correct.

16 MEMBER FISCHER: I'll make this brief.
17 I think it is very feasible. It is already in
18 use as a CMS DFC measure. I don't have anything
19 else to say.

20 CO-CHAIR CROOKS: More comments?

21 (No response.)

22 I think we can go ahead and vote on

1 feasibility.

2 MS. OGUNGBEMI: We are now voting on
3 feasibility for Measure 2979. Your options are
4 1, high; 2, moderate; 3, low, and 4,
5 insufficient. Voting is open.

6 (Voting.)

7 We are down to 19 votes because one of
8 our Committee members stepped out. So, our
9 results are 79 percent high, 21 percent moderate,
10 zero percent low, and zero percent insufficient.
11 Measure 2979 passes on feasibility.

12 MEMBER FISCHER: I think, then,
13 second-to-last is usability and use. I think it
14 is already in use as a DFC measure since 2014.
15 It is approved for the QIP in payment year 2018.

16 Just kind of getting to the most
17 important points, the one thing I think that also
18 comes up in usability -- and we touched upon it
19 briefly, but it is asked specifically here in
20 this script -- is about unintended consequences.
21 Specifically, and the developers acknowledge
22 this, about is there a concern that higher

1 hemoglobins could be targeted, for some of the
2 reasons why we have articulated up to this point
3 in the conversation.

4 I think that they believe that that is
5 less likely, given that oftentimes transfusion
6 avoidance should be satisfactory with hemoglobins
7 even over 10. So, no reason necessary to go over
8 12 or 13. That is the argument or the point I
9 understand from what was documented.

10 What I just would point out, though,
11 is that, previously, if I am correct, there was a
12 QIP measure, right, for hemoglobins greater than
13 12, and that no longer is ongoing. And the new
14 measure is just looking at, you report number of
15 months of hemoglobin and ESA use. There is no
16 hemoglobin cutoff.

17 And I only bring this up because, you
18 know, as time rolls on, the landscape changes. I
19 think the other measures that contextualize this
20 one have changed. And that is why I just wanted
21 to bring that to everyone's attention.

22 CO-CHAIR CROOKS: Okay. Other

1 comments on usability and use?

2 (No response.)

3 Unintended consequences? No?

4 Okay. Let's vote.

5 MS. OGUNGBEMI: We are now voting on
6 Measure 2979, usability and use. Your options
7 are 1, high; 2, moderate; 3, low, and 4,
8 insufficient. Voting is open.

9 (Voting.)

10 Results are 26 percent high, 68
11 percent moderate, 5 percent low, and zero percent
12 insufficient. Measure 2979 passes on usability
13 and use.

14 CO-CHAIR CROOKS: So now, we are ready
15 to vote on accepting the measure, endorsement of
16 the measure.

17 MS. OGUNGBEMI: Yes.

18 CO-CHAIR CROOKS: Suitability for
19 endorsement. Thank you.

20 MS. OGUNGBEMI: We are now voting on
21 2979's overall suitability for endorsement. Your
22 options are 1, yes, and 2, no. Voting is open.

1 (Voting.)

2 Results are 79 percent yes, 21 percent
3 no. Measure 2979 is recommended for endorsement.

4 CO-CHAIR CROOKS: Okay. Thank you,
5 Committee. Thank you for great discussion.

6 We will now take a 10-minute break.

7 (Whereupon, the above-entitled matter
8 went off the record at 2:08 p.m. and resumed at
9 2:20 p.m.)

10 CO-CHAIR ANDERSON: Okay. If we can
11 all get back together, so we can restart?

12 We are going to be starting with 0369,
13 which is the Standardized Mortality Ratio, and
14 Lorien has a conflict. John, Ishir, Peter, and
15 Josh are the reviewers.

16 MEMBER BHAN: So, I am going to lead
17 this off. This is just a frame. This is an
18 existing --

19 CO-CHAIR CROOKS: I'm sorry, we are
20 shortcutting the process.

21 CO-CHAIR ANDERSON: Right.

22 CO-CHAIR CROOKS: Hold that thought.

1 (Laughter.)

2 MEMBER BHAN: Thank you. Thank you.

3 DR. WHEELER: Good afternoon. I'm
4 Jack Wheeler. I'm an economist at the University
5 of Michigan. This is my colleague Claudia
6 Dahlerus, who is a research scientist at the
7 U of M.

8 We have nephrology and statistics
9 expertise in the back of the room, as you have
10 already heard from, and we may be calling on them
11 as we go.

12 The standardized mortality ratio for
13 dialysis facilities was developed by the
14 University of Michigan Kidney and Epidemiology
15 and Cost Center over two decades ago, and it has
16 been in use in the dialysis facility reports
17 since 1995. They received initial NQF
18 endorsement in 2008, and it has been improved
19 substantially over the years, thanks, in part, to
20 the review process established by NQF.

21 These improvements have enhanced the
22 measure's feasibility and usability, and these

1 endorsement criteria are well-supported by its
2 use in public reporting in Dialysis Facility
3 Compare since 2001, and by notable reductions in
4 mortality associated with dialysis patients over
5 the years.

6 Since the last endorsement by NQF in
7 2012, we have made four changes to the
8 standardized mortality ratio. Most specifically,
9 the risk-adjustment model now includes adjustment
10 for 210 prevalent comorbidities, as reported on
11 Medicare claims over the previous calendar year,
12 in addition to the incident comorbidities
13 reported on the medical evidence form.

14 The inclusion of prevalent
15 comorbidities as adjusters is partially in
16 response to comments received from a broad range
17 of stakeholders over the past few years. These
18 stakeholders made the point that adjustment for
19 prevalent comorbidities was necessary to reflect
20 a more timely assessment of the patient's health
21 status.

22 In response to these comments and

1 suggestions, and with the support of CMS, U of M
2 KECK conducted several analyses of potential ways
3 in which prevalent comorbidities could be
4 included in the risk-adjustment model. These
5 analyses informed the work of a Technical Expert
6 Panel in 2015, and the TEP developed a set of
7 recommendations for the inclusion of specific
8 prevalent comorbidities as risk-adjusters in the
9 SMR. Both the process followed by the TEP and
10 all of its resulting recommendations were
11 supported by TEP members with strong consensus
12 and in several cases unanimity.

13 In the development of the revised SMR
14 that is described in the NQF materials, U of M
15 KECK implemented fully and without alteration the
16 TEP recommendations. This changed review is
17 essentially improving the face validity of the
18 SMR.

19 A second change to the SMR is that it
20 pertains to Medicare patients only. This change
21 was supported by the TEP as necessary to enable
22 the use of Medicare claims data to reflect

1 prevalent comorbidities.

2 Third, the risk-adjustment model now
3 adjusts for each incident comorbidity separately
4 rather than through the use of a comorbidity
5 index, as in the past. This change was made for
6 consistency in the handling of incident and
7 prevalent comorbidities.

8 And fourth, the indicators for
9 diabetes from the medical evidence form have been
10 consolidated into more meaningful incident
11 comorbidity adjusters.

12 We look forward to your review of the
13 SMR today. Thank you.

14 CO-CHAIR CROOKS: Okay. Thank you.

15 MEMBER BHAN: So, apologies for my
16 overexuberance in getting started.

17 (Laughter.)

18 As nicely summarized, we are dealing
19 with a previously-endorsed measure. In terms of
20 the evidence, there is a great deal of evidence.

21 Actually, to summarize the measure
22 again, just so we are all on the same page, the

1 measure is a standardized mortality ratio, but it
2 is mentioned that it can also be calculated as a
3 rate. And the rationale is that dialysis
4 patients die at high rates and that high
5 mortality is a less-than-desirable outcome. And
6 so, it is used as the measure here.

7 The numerator is the number of deaths
8 among eligible patients at the facility during
9 the time period. The denominator is the number
10 of deaths that would be expected among eligible
11 dialysis patients. As mentioned, there are
12 numerous covariates that are used for adjustments
13 here.

14 The measure type is an outcome, and
15 data sources are administrative claims and
16 electronic clinical data. And the level of
17 analysis here is at the facility level.

18 So, it is mentioned that the SMR is
19 typically expressed as a ratio, but it can also
20 be calculated as a rate. And so, I think the way
21 I like to frame this is, if you look at the
22 algorithm -- and this is mentioned with the last

1 topic we covered -- the initial question is, does
2 the measure assess a performance on health
3 outcome? I think most people would agree that
4 mortality is a health outcome. And then, is
5 there a relationship between at least one
6 healthcare action, structure, process,
7 intervention, or service, that can influence that
8 outcome? Now there is a great deal of evidence
9 provided here, a lot of, admittedly,
10 retrospective and observational, but some
11 prospective analysis as well, looking at various
12 different factors that are associated with
13 mortality rate. And the way I thought of this
14 was, conversely, if we say, is there nothing we
15 can do to affect the mortality, I would think
16 that most people would probably say that is not
17 accurate.

18 So, given that this is an existing
19 measure, I will stop there and let anyone jump
20 in, if they feel like they need to.

21 MR. LYZENGA: And just to clarify, you
22 do have the option of sort of skipping over and

1 foregoing a vote on evidence, since this was
2 approved by the previous Committee. So, with the
3 Committee's consent, you may do that if you feel
4 that is appropriate.

5 CO-CHAIR CROOKS: Forego the vote is
6 sort of like voting yes, I suppose.

7 CO-CHAIR ANDERSON: Alan has some
8 comments. Alan?

9 CO-CHAIR CROOKS: Alan? Dr. Kliger?

10 MEMBER KLIGER: So, I think if you
11 follow the algorithm, I think that there is no
12 question that it is an outcome measure and there
13 is no question that there are some factors that
14 relate directly to that outcome.

15 So, strictly looking at this
16 algorithm, if that is the way we are going -- and
17 that is what we did with the last one -- I would
18 have to agree with you that we say this is a pass
19 here.

20 However, I again want to raise the
21 concern that we are developing measures that we
22 want to have of utility for clinicians to improve

1 overall care for patients. I still find that the
2 evidence that the mortality rate itself is
3 substantially affected by things that we
4 clinicians actually can manipulate is relatively
5 small, that the vast majority of this outcome,
6 which is perhaps the most important outcome to
7 patients, is determined by factors other than
8 things that we control. And while we surely can
9 have a wider set of comorbidities adjusted for,
10 and that is very helpful in this context, that,
11 nonetheless, if they are the controlling factor
12 and there is only a very small amount of
13 difference that anything that we do makes, then
14 it is an insensitive tool to use for quality
15 improvement.

16 And so, again, we are going to pass
17 this and we are going to go through the
18 discussion quickly, my guess is, but I just need
19 to again register my concern that, as a measure
20 of utility for quality improvement, that I find
21 it to be a very blunt instrument.

22 CO-CHAIR ANDERSON: Andrew?

1 MEMBER NARVA: It is interesting, I
2 think that physicians or providers may not be
3 convinced that they can have a big impact, but I
4 think most patients do. In the sense that this
5 is a patient-centered outcome, not because it is
6 their death, but just because it is a concern of
7 patients, I think it just changes the
8 perspective.

9 My experience, just when I oversaw
10 lots of dialysis units for Indian Health Service,
11 was, when there was a flurry of deaths, the
12 patients were very concerned about whether that
13 reflected a quality difference. And that was the
14 one time you would really get a grassroots
15 question. And so, it is not exactly the way we
16 approach things, but I think patients would like
17 to have this information, would like to know that
18 someone is looking at it.

19 MEMBER HARTWELL: Hi. This is Lori
20 Hartwell. I would just like to chime-in.

21 Just to the comment, just hearing that
22 there is very little ability to change, isn't

1 there improved survival rate with home dialysis
2 and nocturnal dialysis? And this is important to
3 patients. So, I just wanted to throw that out
4 there, and what was the response? You know, that
5 improving mortality, and if more patients would
6 choose those treatments, we might have better
7 outcomes.

8 MEMBER BHAN: And I think one of the
9 tricky things has always been, if you look at
10 observational data, people will critique it and
11 say, "Well, those are observational studies,"
12 "They're retrospective studies," "They're prone
13 to residual confounding." But, yet, the
14 prospective trials are selected populations.
15 They are not generalizable. So, I think it is
16 just a very difficult thing to know for sure what
17 the answer is here.

18 I will note that the NKF did put a
19 comment in saying they do not support this
20 measure because it does not clearly encourage
21 quality improvement or provide meaningful
22 information to patients. And a lot of that was

1 based on comorbidities. Now there is a great
2 deal of adjustment here. There will always be
3 people who argue that it is insufficient. And
4 then, there is a question of what exactly can be
5 done and should we focus more on more specific
6 measures, to Alan's point. But I don't know that
7 there will ever be adequate resolution along
8 those lines.

9 CO-CHAIR ANDERSON: Frank?

10 MEMBER MADDUX: So, I would just like
11 to ask Jack and Claudia a question about, as we
12 think about the life cycle and evolution of this
13 particular measure and we realize that we are
14 moving from dialysis care to broader care of the
15 patient fully that has end-stage renal disease,
16 we will move into an environment where there are
17 many more patient-centered options and goals that
18 patients choose. And so, how will this measure
19 play, as we have progressively more patients that
20 elect to dialyze not for rehabilitative reasons,
21 but for other reasons that may not be
22 commensurate just with length of life?

1 DR. WHEELER: Frank, I'll answer as an
2 economist and, then, maybe turn to my
3 nephrologist colleagues.

4 I think you're right, I mean sort of
5 expanded definitions of the bundle and the CEC,
6 and all we're going toward, will change the way
7 patients think about their care and providers
8 think about the care for sure.

9 I do think that we are always going to
10 want some kind of mortality metric. It will
11 perhaps evolve and be associated with different
12 mixes of care. But I think we are always going
13 to want to track mortality and see how it is
14 going, allow us to evaluate facilities.

15 And I will see if anybody else wants
16 to chime-in there.

17 MEMBER HARTWELL: I'm just curious
18 because this is kind of a new conversation where
19 this wouldn't be a potential measure. How do
20 nursing homes handle it? And as a patient,
21 whenever I look at like a transplant center, I
22 look at the success rate overall. So, how would

1 one determine the success rate? And I understand
2 there is an older population and there might be
3 some palliative care involved. Just for my own
4 knowledge, I would be curious to know.

5 CO-CHAIR CROOKS: So, Lori, what is it
6 that you're asking? Can you be a little more
7 specific?

8 MEMBER HARTWELL: Well, we are
9 discussing this measure on mortality, and I am
10 just surprised that it is not considered
11 important. This is the first I have really heard
12 that conversation. So, it is all new to me.

13 As a patient, this is something that
14 is very important. This is how you can really
15 determine a success rate. Now I understand that
16 we are moving to more integrated care models.
17 Palliative care is becoming a topic of
18 discussion. So, again, you wouldn't want
19 somebody to skew -- you know, keep somebody who
20 doesn't choose to be on dialysis and, then,
21 decide that they need to be to make these
22 measures. So, I do understand that.

1 I'm just trying to absorb what was
2 just said, and I'm speaking outloud right now.
3 So, maybe I don't have a question, if anybody can
4 add --

5 CO-CHAIR CROOKS: Right. Okay. Well,
6 I would reassure you that I don't think anybody
7 is saying the measurement of mortality is not
8 important. I think it is important.

9 What is difficult is which audience is
10 looking at it and what can be done by clinicians
11 to improve it. That is always, you know, from a
12 physician's point of view, is it the most useful
13 to know that your dialysis unit's mortality is a
14 little low? It doesn't tell you exactly what you
15 need to do fix the problem or to improve it. But
16 nobody is saying it is not important, and that in
17 the future, even as healthcare systems evolve, we
18 won't want to keep looking at that, or its
19 converse, which is survival.

20 DR. MESSANA: So, Dr. Maddux, I think
21 it is a great question. We have talked over the
22 phone recently about these kinds of things. And

1 I think you hit on a critical point.

2 We also talked about the difficulty in
3 developing those kinds of metrics and how far off
4 they are. Even after those metrics that evaluate
5 the sensitivity of a facility to patient
6 decisions and what the patient's goals are, there
7 are opportunities to game systems by how one
8 defines or how one presents that information or
9 those data to patients.

10 And so, I agree fully with Jack that,
11 as long as we are in the business of spending the
12 kind of effort we do each year to have people on
13 dialysis, that survival on dialysis is one of the
14 primary metrics. Certainly, how successfully we
15 achieve patient goals is something that is also
16 going to be very important down the road. How
17 long it takes us to get there is the real
18 question.

19 DR. WHEELER: I would just add one
20 more thought. So, the unit of analysis for a
21 mortality ratio or the unit of responsibility,
22 let's say, may evolve in response to some of the

1 factors that you are talking about as well. That
2 makes sense to me.

3 CO-CHAIR CROOKS: Rick?

4 MEMBER KASKEL: Excuse me. Maybe I'm
5 missing something, but there are so many factors
6 here and variables that I'm not seeing that kind
7 of affect the outcomes that you are looking at.

8 For instance, the demographic
9 characteristics of the unit and the facility, how
10 is that standardized here? Innercity, rural,
11 suburban? I mean, is that somehow standardized
12 in this equation, in this analysis?

13 DR. WHEELER: So, we standardize for
14 the demographics, some demographic
15 characteristics of the individual patients, but
16 not the sort of market or area-level of measures
17 that I think you are referring to, at least at
18 this point. We evaluated whether that was a good
19 idea and at this point concluded that it wasn't.

20 MR. LYZENGA: We may want to hold off
21 on that discussion until the validity section.

22 MEMBER WAGNER: Could you just

1 summarize for us what you believe the more robust
2 case-mix adjustment and the elimination of non-
3 Medicare patients does to this measure with
4 respect to the outcomes?

5 DR. WHEELER: Would you mind waiting
6 until we get to validity?

7 MEMBER WAGNER: Oh, okay.

8 DR. WHEELER: Because it is sort of
9 more properly within that category.

10 MEMBER WAGNER: Because I am just
11 worried that, if we rush through this, as people
12 have argued that let's just say this is the same
13 measure, then we will not have that discussion.

14 MEMBER ZARITSKY: I think there will
15 be a lot of discussion on validity because I
16 think my honest opinion is it overmodeled when
17 you look at the details. So, we will get to all
18 of that, but I think we should vote on the
19 evidence. But I think that is going to be one of
20 the easier things.

21 MR. LYZENGA: It sounds like the sense
22 of the Committee is not to skip over the

1 scientific acceptability portions, and we will
2 have some discussion there.

3 I guess we still have the question, do
4 we want to vote on evidence or not? Maybe we
5 should do that by exception. Is there anybody
6 who does want to vote on evidence?

7 CO-CHAIR CROOKS: Right. If you would
8 like to have a vote on evidence, please raise
9 your hand.

10 (Show of hands.)

11 Okay. I'm getting a lot of this.
12 Okay. Let's vote on the evidence. I think that
13 is what the Committee would like to do.

14 MS. OGUNGBEMI: Okay. We are now
15 voting on Measure 0369, Standardized Mortality
16 Ratio for Dialysis Facilities. We are voting on
17 evidence for health outcome measures. Your
18 options are 1, yes; 2, no. Voting is open.

19 (Voting.)

20 Results are 89 percent yes and 11
21 percent no. Measure 0369 passes on evidence.

22 MEMBER BHAN: Okay. So, let's go on

1 to the performance gap here. Here the developer
2 presented SMR data for dialysis facilities, and
3 there was quite a degree of variation where the
4 mean, of course, is 1.02, but the 10th percentile
5 went down to .05 and the 90th percentile went to
6 1.5. That is over the 2010-to-2014 time period.

7 And in terms of disparities, this is
8 a little bit tricky. The developer mentioned, if
9 you look at various different demographic, for
10 example, Hispanic patients have lower mortality
11 than non-Hispanic; whereas, female patients have
12 lower mortality as well than male patients.
13 Although these are included in the adjustment, so
14 that is not really a disparity in the SMR per se,
15 but, clearly, my feeling was that there will
16 always be a performance gap in terms of
17 mortality. But I appreciate there is a variety
18 of opinions on this. But I will let anyone else
19 comment.

20 CO-CHAIR CROOKS: Okay. Any other
21 discussion?

22 (No response.)

1 I would say that the disparities just
2 demonstrates gaps, and that is what we are voting
3 on right now. So, that is a different topic than
4 whether or not or how you adjust.

5 So, let's vote on the presence of the
6 performance gap.

7 MS. OGUNGBEMI: We are now voting on
8 performance gap for Measure 0369. Your options
9 are 1, high; 2, moderate; 3, low, and 4,
10 insufficient. Voting is open.

11 (Voting.)

12 Results are 26 percent high, 68
13 percent moderate, zero percent low, and 5 percent
14 insufficient. Measure 0369 passes on performance
15 gap.

16 MEMBER BHAN: Okay. So, let's move on
17 to reliability. Just as a reminder, the
18 numerator here is the number of deaths among
19 eligible patients at the facility during the time
20 period, and the denominator is the number of
21 deaths that would be expected among eligible
22 dialysis patients at the facility during the time

1 period, given the various adjustments that are
2 detailed extensively.

3 So, the key thing here, since it is an
4 existing measure, are the changes to the measure
5 since the last time. As mentioned by the
6 developer, there are four key changes. One is
7 the model now adjusts separately for each
8 comorbidity rather than using an index. Two is
9 the indicators for diabetes were consolidated
10 from the individual indicators.

11 I think that two more important or
12 more dramatic changes are, No. 1, the adjustment
13 for 210 prevalence comorbidities, instead of just
14 the incident comorbidities from 2728, are now
15 included; and that the measure is now limited to
16 Medicare patients, which should make the data
17 collection a little more reliable, and the data
18 from the first 90 days is not included,
19 therefore.

20 So, I will pause there for any
21 questions or comments.

22 (No response.)

1 So, moving on to some comments on the
2 reliability testing, the developer looked at the
3 degree to which the SMR data was consistent from
4 year to year. If you look at the data, it is
5 fairly consistent from year to year. There is
6 also some data provided -- now this came up with
7 a previous discussion -- on not only the effects
8 over time, but the reliability testing based on
9 the size of the facility.

10 And here there is -- I don't know if
11 we can pull that up on this screen -- if you look
12 at the IURs for the three-year measures, they are
13 overall on the low side, suggesting that there is
14 a good deal of differences that can be attributed
15 to noise. And that is particularly evident for
16 these smaller dialysis units.

17 So, just to give you some numbers here
18 for 2010 -- that is 2013; yes, there we go -- you
19 can see these numbers, we were critiquing numbers
20 that were .5 in the last measure, but these are
21 consistently below .5, until the four-year SMR
22 data was looked at collectively.

1 So, in the previous data you can see,
2 especially in the small units, the numbers are
3 .07, .06, .03, and even across four years, .3.
4 So, that was a little bit of a concern for me,
5 but that is the nature of the data.

6 MEMBER FISCHER: I actually had a
7 question about this, and maybe to the developer.
8 With the STR, the year-to-year data is similar
9 for an aggregate of three- or four-year data.
10 For here, it is much different. You could just
11 pick 2013, right, where it is .10 to .4, but the
12 aggregate four-year is .3 to .73. I didn't
13 review this in-depth, but I was trying to
14 understand how the aggregate four-year values are
15 so different from year-to-year values,
16 particularly in contrast to the measure that I
17 reviewed in detail. And perhaps there is a
18 simple explanation, but I was just curious if the
19 developers had a comment.

20 DR. WHEELER: I'll start.

21 MEMBER FISCHER: So, yes. No, no, you
22 have year-to-year data. Yes, there is no

1 aggregate like over four years.

2 But I guess what is interesting is why
3 -- anyway, I guess one question that just remains
4 for me is why there is such a difference in an
5 annual value versus a four-year composite value.

6 DR. WHEELER: It's principally just a
7 matter of sample size and the very low frequency
8 of mortality in the population relative to, let's
9 say, transfusions, which are much more frequent.

10 Doug, do you have anything more to say
11 about that?

12 DR. SCHAUBEL: No, that's it.

13 CO-CHAIR ANDERSON: Go ahead, Frank.

14 DR. MESSANA: So, mean transfusion
15 rates are about .45, .47, right? I mean, it is
16 not evenly distributed. But transfusion events
17 on average are much more common than death, which
18 is 15-18 percent, something like that, and I am
19 told that it affects these calculations. They
20 are very sensitive to the numbers.

21 CO-CHAIR ANDERSON: Frank?

22 MEMBER FISCHER: But this measure is

1 an annual reported measure, correct?

2 CO-CHAIR ANDERSON: Yes.

3 MEMBER FISCHER: So, in other words,
4 the ones that are the most relevant, when you
5 think about reliability, would be the year-to-
6 year values.

7 DR. DAHLERUS: So, what is reported on
8 Dialysis Facility Compare's four-year measure?

9 CO-CHAIR ANDERSON: Frank?

10 MEMBER MADDUX: I think, Michael, from
11 just observing a lot of clinics over time, there
12 are more than a few clinics that will have
13 exceedingly good scores for a few years and build
14 up, essentially, a supply of older and older,
15 longer vintage dialysis patients that ultimately
16 die, and they will, almost predictively, go down
17 if they have two or three exceptional years. Now
18 that may not be what you all see statistically,
19 but this is not inconsistent with what my
20 observations have been in a large population of
21 facilities.

22 CO-CHAIR CROOKS: Well, I, for one, am

1 very troubled by the low reliability of this
2 measure, especially the one-year measurement
3 where, even in a large facility, your variation
4 -- I may not be interpreting this right -- but it
5 is 50/50 chance that it is actually due to
6 something you are doing in your unit versus
7 noise. And it is nice to hear that it is
8 reported as four-year where the reliability does
9 go up, but the measure, as written, is a one-
10 year, not a four-year.

11 DR. DAHLERUS: Either. It could be
12 calculated either --

13 CO-CHAIR CROOKS: Either? It could be
14 either way?

15 CO-CHAIR ANDERSON: Michael?

16 MEMBER SOMERS: Even with four-year,
17 I mean, if you look at the number of facilities,
18 and 60 percent of the facilities are going to
19 fall either in the small or the medium
20 categories, and they have IURs that are quite
21 low. So, it is hard to be enthusiastic about
22 something that may not be reliable for 60 percent

1 of facilities.

2 CO-CHAIR CROOKS: So, other comments
3 on reliability?

4 (No response.)

5 Does this Committee feel ready to vote
6 on reliability? I guess they are.

7 MS. OGUNGBEMI: We are now voting on
8 reliability for Measure 0369. Your options are
9 1, high; 2, moderate; 3, low, and 4,
10 insufficient. Voting is open.

11 (Voting.)

12 Results are 5 percent high, 16 percent
13 moderate, 74 percent low, and 5 percent
14 insufficient. Measure 0369 fails on reliability.

15 MR. LYZENGA: So, that is, again, a
16 must-pass criterion. The measure will not move
17 forward. We can, again, provide some feedback to
18 the developers if we have any thoughts on how
19 they might improve the measure, if they would
20 like to bring it back to us for consideration.

21 MEMBER ZARITSKY: Just one thing I
22 noticed, and a lot of the outside groups

1 commented, that you might have gone a little too
2 far with your modeling; that you look at some of
3 the -- you know, there's some strange stuff that
4 pops up when you include so many different
5 variables, like thyroid cancer is protective. It
6 appears to be overmodeled.

7 And I think that most of us agree that
8 this is, you know, a valid, I consider it a valid
9 measure. Especially patients want to know what
10 the -- maybe not the rate; they want to know the
11 rate versus the ratio. But it seems like, for
12 the larger units, you do have a good four-year --
13 you know, .7 is adequate. So, maybe it needs to
14 be restructured for larger groups.

15 MEMBER BHAN: Yeah, I just want to
16 emphasize that it seems like the main hangup here
17 was this IUR. So, restricting to four-year data
18 may be a way to deal with that.

19 MEMBER KLIGER: Can I just underline
20 the comments about thinking about this as a rate
21 rather than a ratio? Because, obviously,
22 mortality is important; it is important to all of

1 us. But, if we are focused on the way patients
2 are seeing it and what patients are responding
3 to, then the rate is going to be far more
4 valuable to them than is a ratio.

5 DR. WHEELER: Thank you.

6 A couple of responses. First of all,
7 the numbers of comorbidities, the 210 additional
8 prevalent comorbidities, you find that as
9 generally an improvement. But I think it is
10 important to look at the comorbidities taken as a
11 whole and their effect, rather than some of the
12 individual coefficients.

13 The TEP did --- the goal of the TEP
14 was to include all relevant comorbidities that
15 might not be under the control of the facility,
16 and that was kind of the tenor of their
17 discussion. And so, we did that in terms of our
18 modeling, just as one response.

19 A second question I would ask is, if
20 we had offered this as a measure that was only a
21 four-year measure, would the numbers that you see
22 here in terms of reliability have carried the day

1 or would there still be kind of a level of
2 reliability that is insufficient?

3 And I'll get to your question in a
4 second.

5 CO-CHAIR ANDERSON: John? John?

6 MEMBER WAGNER: So, I just will
7 respond to that and will ask my question. I
8 would be concerned, since we don't have the data,
9 what the medium- and small-sized IUR, if combined
10 together, what their IUR would be over a four-
11 year period as well. Because, again, we are
12 talking about 60 percent of the facilities may
13 have a very high noise ratio compared to signal.

14 I want to, again, pose the question I
15 asked at the outset because I suspected we would
16 get to this point. What is, in fact, with this
17 what some have termed "overmodeling of the data,"
18 has that actually reduced the IUR compared to the
19 previous? And the elimination of the Medicare,
20 rather elimination of the non-Medicare
21 population, has that impacted these data in a
22 meaningful way?

1 DR. WHEELER: We did look at the
2 effect of including or adding the 210 prevalent
3 comorbidities on the IURs, and, yes, there was an
4 effect; that does lower the IURs from what it
5 would be if we didn't adjust for all the
6 prevalent comorbidities.

7 In terms of the tradeoff with
8 Medicare, I don't think we did look at the effect
9 of excluding Medicare on the reliability measure
10 analyses that we did. Okay?

11 Sorry, was that responsive to your
12 question? Okay.

13 In terms of the rate versus ratio, we
14 could convert the ratio into rate by applying the
15 national average, and that is the way Hospital
16 Compare does it. It seems meaningful. And there
17 are reasons for us to use a ratio approach that,
18 again, have to do with the rare event, relatively
19 rare event of mortality and also hospitalization,
20 which we will talk about in a minute. So, that
21 is the reason we do the ratio, yes.

22 MEMBER KLIGER: I understand the

1 rationale.

2 DR. WHEELER: Okay good.

3 MEMBER KLIGER: And to a scientist,
4 that would be clear, or to a clinician, I
5 believe. But, to our patients, I think it would
6 be perhaps more useful to have a rate.

7 DR. WHEELER: Right.

8 CO-CHAIR ANDERSON: Michael?

9 CO-CHAIR CROOKS: Michael, you had
10 your card up?

11 CO-CHAIR ANDERSON: Oh. That's fine.

12 DR. DAHLERUS: I did want to clarify
13 that it will be reported as a rate in the future
14 on Dialysis Facility Compare for the purpose of
15 providing something interpretable to patients.

16 CO-CHAIR CROOKS: Okay?

17 MEMBER LATTS: Can I just ask a quick
18 question?

19 CO-CHAIR CROOKS: Yes.

20 MEMBER LATTS: I'm just wondering what
21 the sort of practical implications are of this
22 not being an approved NQF measure. I mean,

1 obviously, CMS is going to keep using it, right?

2 CO-CHAIR CROOKS: Well, our turnaround
3 time used to be four years before the Committee
4 would meet again. Now we are a standing
5 committee. So, I suppose the implication is, if
6 this can be improved and the reliability
7 improved, you know, we may not have to wait that
8 long.

9 But what do you see as the -- you are
10 asking what are the negative consequences of it?

11 MS. SAMPSEL: But, you know, I also,
12 just as a reminder, this is this step in the
13 process. We still have public comment. This
14 would go out for public comment. It still
15 included in the draft report for public comment.
16 And then, you could also ask for a
17 reconsideration request.

18 So, you know, we have heard you say
19 that this is already a four -- you know, it is
20 implementable or operationalizable as a four-year
21 reportable measure. And so, if you can adjust
22 anything that you have heard from the Committee

1 and, thus, want to ask for a reconsideration, you
2 can do that during public comment.

3 CO-CHAIR ANDERSON: All right. Moving
4 on to the Standardized Hospitalization Ratio, it
5 is Stuart, Franklin, Karilynne, and Andrew.

6 And we will hear from our measure
7 developer first.

8 DR. WHEELER: Thank you.

9 This will be a brief introduction.
10 The Standardized Hospitalization Ratio was also
11 developed by the University of Michigan KECK over
12 two decades ago. It has been included in the
13 Dialysis Facility reports since 1995. It
14 received initial NQF endorsement in 2011, and it
15 also has been improved substantially over the
16 years.

17 The changes that we have put in since
18 the 2011 endorsement are the same ones that we
19 had for the SMR with one exception. The SHR was
20 always about Medicare patients only. So, that
21 change has not been made. But we did, as with
22 the SMR, we did add 210 prevalent comorbidities

1 in response to stakeholder requests and the work
2 of the TEP. So, those are our main changes.

3 CO-CHAIR ANDERSON: All right. Who is
4 taking the lead on this one?

5 MEMBER GREENSTEIN: I guess I am. Not
6 sure why they're certain, but that's all right.

7 Anyway, so this is a measure, as was
8 mentioned, that has been reported previously. As
9 was mentioned, the hospitalization rates vary
10 among the chronic dialysis units. Even though
11 there has been a decline in the general
12 population, in the dialysis patients we have not
13 seen the same kind of decline.

14 In addition, the USRDS Annual Report
15 for 2015 showed that approximately half of all
16 the dialysis patients continue to have
17 hospitalizations due to factors such as
18 cardiovascular infections and diseases.

19 Programs that were developed to impact
20 upon hospitalization rates included catheter
21 usage and other things that have clearly impacted
22 upon the hospitalization rates. And here, I

1 guess the real question was that this is clearly
2 health outcome process that we are looking at,
3 not using the word "process" though, but health
4 outcome. And the question was here whether or
5 not we should just go straight to an endorsement
6 since it was previously endorsed versus should we
7 go through a complete review, just like we did on
8 the SMR. I am curious to see what everybody is
9 going to say, given that the SMR was knocked out.

10 So, with that, I'll start from there.

11 CO-CHAIR ANDERSON: So, shall we vote
12 on whether to pass or not? On evidence? I'm
13 sorry. On evidence?

14 Any comment? Any further comments?

15 Yeah, Alan?

16 MEMBER KLIGER: If you follow the
17 algorithm, it has to be passed.

18 CO-CHAIR ANDERSON: Yeah. Good
19 comment.

20 MR. LYZENGA: Is there anybody who
21 would like to vote?

22 So, call for a vote.

1 MS. OGUNGBEMI: We are now voting on
2 Measure 1463, Standardized Hospitalization Ratio
3 for Dialysis Facilities, and we are voting on
4 evidence for health outcome measures. Your
5 options are 1, yes; 2, no. Voting is open.

6 (Voting.)

7 We are waiting on one more vote.
8 Could everyone just point and click one more
9 time? Thank you.

10 (Voting.)

11 Got it.

12 Results are 95 percent yes and 5
13 percent no. Measure 1463 passes on evidence.

14 CO-CHAIR ANDERSON: Okay. Moving on.

15 Oh, turn your microphone on.

16 MEMBER GREENSTEIN: So, we're moving
17 on to -- what's that? Gap, right, let me just
18 bring up my computer, so I can read it easily.

19 The developer mentions that there is
20 variations across facilities and that race and
21 ethnicity have shown to be predictors of
22 hospitalization rates, and they felt that there

1 was a gap, which appeared to follow through from
2 the comments from all the people.

3 CO-CHAIR ANDERSON: Any questions for
4 the developer or further comments? Yes, Frank?

5 MEMBER MADDUX: So, I have a question
6 for Jack and Claudia. We know there are a lot of
7 probably covariates that may relate to
8 hospitalization rates. I'm just wondering how
9 extended you have gone in your adjustment for
10 those geographies and other such things.

11 DR. WHEELER: Well, again, we didn't
12 adjust for geography. We did adjust for patient
13 characteristics. As noted, we adjusted for a
14 large number of patient comorbidities and age and
15 sex. Basically, yeah, we did not adjust for true
16 geography, but we did evaluate whether geographic
17 characteristics were something we wanted to
18 adjust for. Measures such as the per-capita
19 income in a zip code and educational levels in a
20 zip code or unemployment, and those sorts of
21 characteristics, we did look at those.

22 CO-CHAIR CROOKS: You did look at

1 those?

2 DR. WHEELER: Yes.

3 CO-CHAIR CROOKS: Okay.

4 DR. DAHLERUS: Just to elaborate on
5 Jack's answer, so we evaluated area-level
6 socioeconomic status as well as patient-level
7 SCS, in addition to demographic factors. And
8 those results are reported in the testing
9 section. But the bottom line is area-level
10 factors had very little impact on SHR, and
11 especially when you look at flagging with and
12 without those adjustments.

13 CO-CHAIR ANDERSON: Any further
14 discussion?

15 (No response.)

16 Are we ready for the vote? All right.

17 MS. OGUNGBEMI: We are now voting on
18 performance gap for Measure 1463. Your options
19 are 1, high; 2, moderate; 3, low, and 4,
20 insufficient. Voting is open.

21 (Voting.)

22 Results are 37 percent high, 63

1 percent moderate, zero percent low, and zero
2 percent insufficient. Measure 1463 passes on
3 performance gap.

4 CO-CHAIR ANDERSON: All right.
5 Reliability.

6 MEMBER GREENSTEIN: Just give me one
7 second. My computer did a funny thing. Yes, let
8 me get to where it is.

9 In terms of reliability, the developer
10 assessed the degree to which the standard
11 hospitalization rate was consistent from year to
12 year using data on hospitalizations among the
13 patients, and the developer stated the measure is
14 based on complete data and is not subject to
15 judgment or rate of variability. Any variability
16 was related to some noise evidently. And they
17 did throw in now comorbidities to go into the
18 analysis. So, most of the comments were that it
19 was felt that reliability was good and there were
20 no concerns, with the overall IUR being in the
21 .70 range.

22 CO-CHAIR ANDERSON: Any comments or

1 questions?

2 (No response.)

3 Are we ready to call for the vote?

4 MS. OGUNGBEMI: We are now voting on
5 reliability for Measure 1463. Your options are
6 1, high; 2, moderate; 3, low, and 4,
7 insufficient. Voting is open.

8 (Voting.)

9 Results are 26 percent high, 68
10 percent moderate, 5 percent low, and zero percent
11 insufficient. Measure 1463 passes on reliability.

12 CO-CHAIR ANDERSON: And validity,
13 moving on?

14 MEMBER GREENSTEIN: So, the validity
15 was assessed using data on hospitalizations as
16 well as other quality measures over a three-year
17 period by examining its covariability as well as
18 by examining the relationship of overall
19 hospitalization measures with measures that were
20 more directly focused on specific causes.

21 And the validity was tested with
22 results indicating correlation to IUR. We

1 officially standardized modality rate. And for
2 the most part, the comments were that validity
3 was supposed to correlate in terms of this also.

4 CO-CHAIR ANDERSON: Any questions for
5 the developers or further comments?

6 (No response.)

7 All right. Let's call for the vote
8 for validity.

9 MS. OGUNGBEMI: We are now voting on
10 validity for Measure 1463. Your options are 1,
11 high; 2, moderate; 3, low, and 4, insufficient.
12 Voting is open.

13 (Voting.)

14 Results are 32 percent high, 68
15 percent moderate, zero percent low, and zero
16 percent insufficient. Measure 1463 passes on
17 validity.

18 CO-CHAIR ANDERSON: All right. Moving
19 on to feasibility?

20 MEMBER GREENSTEIN: So, feasibility.
21 I think, for this, again, there were no comments.
22 They felt that the data elements were fairly well

1 defined in electronic form and generated and
2 collected so that there was no problem with
3 feasibility. And we have no comments, either, on
4 this.

5 CO-CHAIR ANDERSON: Any further
6 questions or comments for discussion?

7 (No response.)

8 All right. Call for the vote.

9 MS. OGUNGBEMI: We are now voting on
10 feasibility of Measure 1463. Your options are 1,
11 high; 2, moderate; 3, low, and 4, insufficient.
12 Voting is open.

13 (Voting.)

14 Results are 74 percent high, 26
15 percent moderate, zero percent low, and zero
16 percent insufficient. Measure 1463 passes on
17 feasibility.

18 CO-CHAIR ANDERSON: And use and
19 usability.

20 MEMBER GREENSTEIN: So, usability, the
21 measure is publicly reported nationally, Dialysis
22 Facility Compare, and the standard

1 hospitalization ratio measures/incorporates risk-
2 adjustment technology that levels the field for
3 different size units. And therefore, it was felt
4 to be a reasonably usable result.

5 CO-CHAIR ANDERSON: Any further
6 discussion or comments?

7 (No response.)

8 All right. Call for the vote.

9 MEMBER MADDUX: I have a question.

10 CO-CHAIR ANDERSON: Oh, I'm sorry.

11 MEMBER MADDUX: So, can you all just
12 comment and expand a little bit on the discussion
13 that you had around the relationship between SHR
14 and SRR? Interrelationship seems fundamental if
15 they are both going to be used because they are
16 going to run together.

17 DR. DAHLERUS: So, we considered them
18 certainly related, but also complementary in
19 terms of assessing facility management of
20 patients in terms of preventing hospitalizations
21 or preventing a readmission after a patient is
22 discharged from the hospital.

1 So, while there is overlap, we don't
2 think that they are measuring exactly 100 percent
3 of the same thing. So, we are making an
4 assumption that there are things that the
5 facilities can do to prevent an unnecessary
6 hospitalization, and that there are things
7 related to care coordination that should happen
8 after a patient is discharged from hospital in
9 order to prevent a readmission.

10 MEMBER MADDUX: And have you studied
11 statistically the impact on the SRR from an
12 improved index hospitalization rate?

13 DR. DAHLERUS: I'm not sure I quite
14 follow what you are asking.

15 MEMBER MADDUX: Clinically, when we
16 focused on a lot of care coordination activities
17 around avoiding readmissions, one of the
18 correlates that we saw was reduced index
19 hospitalizations --

20 DR. DAHLERUS: Uh-hum.

21 MEMBER MADDUX: -- which seems odd,
22 but, in fact, happened. And so, I'm just curious

1 if there's been any way that you have had more
2 broadly to analyze just the interrelationship of
3 affecting one that may have impact on the other.

4 DR. DAHLERUS: And how that impacts
5 the other?

6 MEMBER MADDUX: Yes.

7 DR. DAHLERUS: We haven't studied that
8 extensively.

9 CO-CHAIR ANDERSON: Any further
10 discussion?

11 (No response.)

12 All right. We're calling for the
13 vote.

14 MS. OGUNGBEMI: We are now voting on
15 usability and use for Measure 1463. Your options
16 are 1, high; 2, moderate; 3, low, and 4,
17 insufficient. Voting is open.

18 (Voting.)

19 Results are 42 percent high, 58
20 percent moderate, zero percent low, and zero
21 percent insufficient. Measure 1463 passes on
22 usability and use.

1 CO-CHAIR ANDERSON: All right. Oh,
2 now for the overall vote for suitability for
3 endorsement.

4 MS. OGUNGBEMI: We are now voting for
5 Measure 1463's overall suitability for
6 endorsement. Your options are 1, yes, and 2, no.
7 Voting is open.

8 (Voting.)

9 Results are 100 percent yes and zero
10 percent no. Measure 1463 passes on its overall
11 suitability for endorsement.

12 CO-CHAIR ANDERSON: All right.
13 Andrew, the discussion for the NQF Measure --

14 DR. WHEELER: I just want to thank the
15 Committee very much for your comments and
16 suggestions. Thank you.

17 CO-CHAIR ANDERSON: -- Medication
18 Reconciliation for Patients Receiving Care at a
19 Dialysis Facility.

20 MR. LYZENGA: Yes. So, as I mentioned
21 in my email to the group, this measure will be
22 considered by the Patient Safety Standing

1 Committee at NQF, who typically has, sort of
2 oversees our portfolio of, well, a range of
3 patient safety measures, but including medication
4 reconciliation measures. We have some other
5 medication reconciliation measures in their
6 portfolio and thought it best to keep this
7 associated with those for things like
8 harmonization purposes and just so we had some
9 consistency.

10 But we acknowledge that there was not
11 specific renal expertise on that Committee,
12 although a pretty broad range of expertise in
13 other areas and in patient safety generally. So,
14 agreed with the developer of this measure that it
15 may be useful to get some input from this
16 Committee on the measure, and particularly if
17 there are considerations that would be specific
18 to the dialysis patient community.

19 It is a fairly straightforward
20 reconciliation measure, but it would be helpful
21 to know if there is anything that the Safety
22 Committee should keep in mind during their

1 review, if there is anything that you would tell
2 them from your perspective as renal experts.

3 And I believe we have the developer on
4 the line here as well, if she wants to just give
5 a quick introduction and explanation of the
6 measure, and see if she has any questions,
7 specific questions, that she would like answered.
8 That is Lisa McGonigal.

9 Lisa, are you on?

10 DR. MCGONIGAL: Yes. Yes, I'm on.
11 Can you hear me okay?

12 MR. LYZENGA: We can.

13 DR. MCGONIGAL: Okay, great. All
14 right.

15 So, I am also joined today by Dr.
16 Robyn Nishimi. Again, I'm Lisa McGonigal from
17 the Kidney Care Quality Alliance, or KCQA.

18 Again, just thank you for taking the
19 time today to lend your expertise and to provide
20 your input on this measure as it is being
21 considered by the Patient Safety Standing
22 Committee in their project.

1 So first of all, just an overview.
2 This is, again, medication reconciliation for
3 patients receiving care at dialysis facilities.
4 It is developed by the Kidney Care Quality
5 Alliance. It is specified at the level of the
6 dialysis facility, which makes it unique among
7 measures contained in NQF's current medication
8 reconciliation measure portfolio.

9 The measure is applicable to all
10 patients permanently assigned to a dialysis
11 facility. And it assesses the percentage of
12 patient months for which medication
13 reconciliation was performed and documented by an
14 eligible professional. And for the purposes of
15 this particular measure, the eligible
16 professional is assigned as a physician, an RN,
17 an advanced practice RN, physician's assistant,
18 pharmacist, or pharmacy technician.

19 Then, in regards to the importance of
20 the measure, as you all well know, medication
21 management is a critical safety issue for all
22 patients, but especially so for patients with

1 ESRD. These individuals often require 10 or more
2 medications. They take an average of 17 to 25
3 doses per day. They usually have numerous
4 comorbid conditions, have multiple healthcare
5 providers and prescribers, and they undergo
6 frequent medication regime changes.

7 Also, medication-related problems
8 contribute significantly to the approximately \$40
9 billion in public and private funds that are
10 spent annually on ESRD care in the U.S.

11 So, in developing the measure, we
12 first examined existing medication reconciliation
13 metrics and considered how to create a measure
14 that is similarly-feasible and that doesn't
15 unduly burden the provider that also goes beyond
16 a single-component checkbox measure.

17 So, rather than seeking a single yes-
18 or-no checkbox that medication reconciliation was
19 performed for a given patient in a given month,
20 we have developed a unique measure as compared to
21 other NQF-endorsed med rec measures that requires
22 multiple elements to be met to be counted as a

1 success for the facility.

2 But, in addition to attestation that
3 all known medications are reconciled by an
4 eligible professional and the date that the
5 reconciliation took place, we also require that
6 the identity of the eligible professional be
7 indicated, and we specifically design what must
8 be addressed during the reconciliation process.

9 Testing and feasibility. The measure
10 was tested using data from three KCQA member
11 dialysis organizations. Each had the capacity to
12 provide retrospective analyses from a data
13 warehouse or repository.

14 Testing involved approximately 5,300
15 facilities, and there were slight differences,
16 depending on the month of the study, and
17 approximately 328,000 patients in each of the six
18 months of the study, which was conducted from
19 April through September of 2015. So, we had a lot
20 of facilities and a lot of patients in the study.

21 Empiric testing using the data
22 binomial method, which is at the measure score

1 level, was conducted and demonstrated that the
2 measure is reliable and that the measure
3 components can be collected. And validity testing
4 was done, and the measure was judged as being
5 able to distinguish good from poor quality.

6 So, with that just brief overview, I
7 will turn the floor over to you guys for your
8 discussion, and feel free to ask any questions.

9 CO-CHAIR ANDERSON: Andrew?

10 MEMBER HARTWELL: This is Lori
11 Hartwell. I have a question.

12 Part of the reconciliation process, is
13 time of day considered in the reconciliation
14 process? It could just be helpful. Like you
15 shouldn't take blood pressure medicine before
16 dialysis and the time of day you're supposed to
17 take your phosphate binder, you know, you're
18 supposed to take it 15-20 minutes after you eat.
19 Is that part of the reconciliation process?

20 DR. NISHIMI: Lori, this is Robyn.

21 No, that would be under a different
22 measure, part of the review process. So, that

1 kind of detail isn't encompassed by the
2 reconciliation measure.

3 CO-CHAIR ANDERSON: Andrew?

4 MEMBER NARVA: I think dialysis
5 patients are probably the perfect storm of lack
6 of interoperability of electronic healthcare
7 platforms. And, I think it would be very
8 possible to check off the box in good conscience
9 and actually not have very good reconciliation.

10 I wasn't able to read the whole
11 measure because I couldn't open it until just
12 now. But how did you validate the reconciliation
13 to the actual medications that the patients were
14 taking? Did you actually have some way of
15 validating that with looking at the actual
16 bottles of medication or how was that done? Or
17 was it done?

18 DR. NISHIMI: No, we used a face
19 validity approach at the measure level. We did
20 not validate the data at that level. I understand
21 your concern.

22 MEMBER NARVA: My concern is that I

1 think this is critical, but it is possible you
2 could have this measure and it not make a big
3 impact because the actual reconciliation is not
4 very high because the bar is not very high. And
5 I don't know if there would be some way to build
6 into it something that would move more towards
7 validating that you actually have a true
8 reconciliation. Because any of us ---

9 DR. NISHIMI: Sure.

10 MEMBER NARVA: You know, most patients
11 see many different providers and it is clearly a
12 real problem, even when you try to reconcile
13 medications.

14 DR. NISHIMI: Sure. I understand the
15 concern, and that was a concern of us as
16 developers, but we did feel that this was the
17 place to start, even at this level. We described
18 in terms of the actual performance, the range of
19 performance was zero percent in a facility in any
20 given month to 100 percent. And obviously, over
21 time one would hope to assess the quality of the
22 reconciliation, which is what I believe you are

1 speaking to. But this is viewed as a starting
2 point for medication reconciliation in this
3 population.

4 I can't hear what is going on now. I
5 don't know.

6 MEMBER LENNING: Okay. Can you hear
7 me now? Aha.

8 I would just like to raise the thought
9 around where is the indication that there is a
10 conversation with the patient. I know we have
11 many medication reconciliation measures that do
12 involve that conversation and true med
13 reconciliation is not solely comparing lists and
14 lists from other providers. But you can only
15 have true reconciliation when you have a
16 conversation with that patient about the
17 medications. You don't know what they truly are
18 taking if it is just a prescription. They can
19 have the prescription and not be using the
20 medication.

21 So, I would just caution that perhaps
22 there needs to be more consideration about that

1 conversation. Thank you.

2 DR. NISHIMI: Yes, we appreciate that
3 comment. We actually developed a trio of
4 measures, a pure medication documentation
5 measure, which is, for lack of a better term, the
6 sort of middle step in our measure set, which was
7 medication reconciliation. And then, the
8 medication review measure would really address
9 that. And the group's feeling was at this point
10 we should advance the middle step, which was the
11 medication reconciliation measure.

12 But we don't disagree and we actually
13 developed a review measure, which, obviously, has
14 much more patient interaction, but that was not
15 the measure that was advanced as the first step
16 for this population.

17 CO-CHAIR CROOKS: Who's next? Alan?
18 Michael?

19 MEMBER FISCHER: My question for the
20 developer is, in order to meet this measure, my
21 understanding is you would have to do med rec
22 every month, regardless of whether a patient has

1 been hospitalized or not. And I was just
2 curious, just thinking about, as we have talked
3 about the other instruments that patients are
4 completing, you know, how long on average did it
5 take, or do you have an idea, did it take to do
6 this for each patient, given the number of
7 medications they are taking each month? And kind
8 of what was the feedback from the patients or
9 their caregivers, as the case may be, about doing
10 this every month?

11 I mention this because we have a
12 freestanding unit where we have a PharmD who does
13 do this, and you get mixed feedback. And I would
14 just be curious what the developer's experience
15 was in their course of their preliminary data
16 analysis.

17 DR. NISHIMI: We didn't specifically
18 assess an issue of time burden, if you will, but
19 there wasn't any real pushback. The fact that
20 when we tested this in, you know, the several
21 thousand facilities and that, it was a zero to
22 100 percent. And it told us that, in fact, there

1 are some or several that are doing this monthly.
2 So, that did not seem to be a consideration when
3 we tested it.

4 MEMBER KLIGER: So, just again a
5 clarification. It still sounds to me like it
6 basically is an attestation. It is an
7 attestation with a datestamp on it perhaps, but
8 it is attestation.

9 So, the difficulty, obviously, is that
10 all of us -- I mean, I'm guilty. I sit in the
11 Epic system and I frequently do attestation to
12 that med rec. And , you know, I sort of have a
13 look at the list and I say, "Yes." I mean, I'm
14 guilty; I do it.

15 So, I wonder in the development of
16 this measure if you have had the opportunity to
17 actually observe or see what med rec really looks
18 like outside of the attestation.

19 DR. NISHIMI: Again, we did not look
20 at sort of the data element level, if you will,
21 quality beyond the attestation. We relied on the
22 attestation of qualified professionals that this

1 was done.

2 MEMBER KLIGER: Yes. Just a quick
3 followup, which is that I personally agree with
4 you that this is a really important first step
5 and it is part of a series of measures which
6 include engagement of the patient. I think that
7 that is important.

8 But I think we all need to recognize
9 that an attestation alone, as we mature in our
10 approach to this, is not going to be sufficient.
11 And we should be thinking about, and perhaps the
12 developer should be thinking about, ways to
13 improve the measure other than it being a pure
14 attestation.

15 DR. NISHIMI: Yeah, and I can report
16 that that's exactly the kind of conversation that
17 the KCQA had and that this was, indeed, a first
18 step, and an evolution will be necessary as we go
19 forward.

20 CO-CHAIR CROOKS: This is Peter Crooks.

21 A couple of comments. Yes, that is a
22 baby step, and there are other medical records to

1 reconcile, too. There is what the patient is
2 taking. There is what the dialysis unit list
3 says. There is a pharmacy list in one or more
4 pharmacies. If they have an electronic medical
5 record such as we have at Kaiser, that may be
6 different.

7 Within Kaiser, the pharmacy and the
8 one that the doctors use is all the same. And
9 then, whether they go to a cardiologist or they
10 go to whatever provider, we are all looking at
11 the same medicine list, which is much better than
12 it is in the non-Kaiser world where every
13 physician is going to have their own medication
14 list. So, it becomes infinitely complex to try
15 to resolve all of those short of one common
16 medical record.

17 We do have to, in order to close an
18 account, we have to check off -- and this is in
19 Epic, the same thing, right? -- and our lawyers
20 told that, as long as you've looked at the
21 medicines that are relevant to what you're taking
22 care of, so the blood pressure pill that day or

1 something, then we can check the box off and
2 we're covered.

3 So, the comment I really wanted to
4 make is ways to validate. This is maybe step two
5 or step three. But you can't go to the patient's
6 house, I don't suppose, and watch them for 48
7 hours and mark down everything they do, as the
8 optimal validation method.

9 But, short of that, a patient diary
10 taken for several days might be a nice way to try
11 to validate that what you're actually getting at
12 the dialysis unit is close to what they are
13 taking at home, a more expensive proposition.
14 And what would motivate patients to do that, I
15 don't know. But I am trying to help think of a
16 validity test that I would find worthwhile and
17 convincing.

18 End of comment.

19 DR. NISHIMI: Thanks. Appreciate it.

20 MEMBER KASKEL: Will this involve
21 under 18? Will this population be under 18?

22 DR. NISHIMI: This is an all-patient

1 measure.

2 MEMBER KASKEL: So, how are you going
3 to assess the infant or a caretaker for an infant
4 or a child?

5 DR. NISHIMI: Well, if we were doing
6 the type of validation that Peter just indicated,
7 we would have to create a protocol that involved
8 proxy reporting, I presume. But, as part of this
9 particular measure, we had a representative from
10 ASPN and it was judged that it was also important
11 for the pediatric population. So, it is an all-
12 patient measure.

13 MEMBER KASKEL: Okay.

14 CO-CHAIR ANDERSON: Frank?

15 MEMBER MADDUX: So, I would just make
16 a comment and reemphasize that I think it is
17 vitally important that we recognize there's a
18 series of steps here, because figuring out where
19 the real source of truth is on medications is not
20 easy.

21 I think there are steps with the
22 evolution of Surescripts and other things to

1 understand what has been filled. I think there
2 are other steps that have got to include what was
3 mentioned previously about talking to the
4 patient, reviewing what is happening there.

5 And it just strikes me that, even
6 though this may be a baby step, it is going to be
7 important that somehow we get started with this
8 because it is a big tree to put your arms around.
9 And somewhere we are going to need to sort of get
10 off the ground to start with.

11 So, it strikes me that one of the
12 opportunities for a measure like this, even as an
13 attestation, is to potentially embed a greater
14 demand to look at one of these resources, whether
15 it is a Surescripts or it is some other resource
16 that looks across organizations and prescribing
17 providers at what all has been filled, regardless
18 of whether it is just in the nephrology world or
19 the cardiology world or the pulmonary world, or
20 where it is. And that is an opportunity with
21 this part of the measure, I think, to actually
22 create that kind of demand, getting to some of

1 the other things, hopefully, sooner after that.

2 CO-CHAIR ANDERSON: Michael?

3 MEMBER SOMERS: I just wanted to
4 comment that, for each medication, you are asking
5 for nine pieces of information, and three of
6 those have to do with information about the
7 medicine that has already been discontinued. So,
8 I guess in the best of all possible worlds you
9 would want to know all that information about the
10 discontinued medication. But, since the main
11 purpose of the reconciliation is to get an idea
12 of what they are taking now, I'm not sure those
13 data elements may be as worthwhile, especially
14 since you tell us that "unknown" is an acceptable
15 response.

16 DR. NISHIMI: Thanks. We will take
17 that back to the group going forward as a
18 potential modification.

19 CO-CHAIR ANDERSON: I just have a
20 clarification question. You're talking about
21 medication reconciliation and, then, you talk
22 about medication management. And I want to make

1 sure we are on medication reconciliation versus
2 including medication management because they are
3 two very different things.

4 Pardon?

5 DR. NISHIMI: Yes, we consider the
6 domain to be medication management, which KCQA
7 had three candidate measures, one on
8 documentation, one on reconciliation, this
9 measure, and one on review. And the whole
10 process was viewed as medication management, but
11 the measure is for reconciliation.

12 CO-CHAIR ANDERSON: Okay. Thank you.

13 Any further questions for the
14 developer?

15 (No response.)

16 Can I ask one more thing? Back when
17 you have the criteria that you have listed for
18 medication reconciliation, it was my
19 understanding when I was reading it, if all the
20 elements were not available, even though you
21 could say "unknown," it would fail. And so, I'm
22 concerned about -- can you explain that a little

1 bit more in terms of what does that mean?

2 DR. NISHIMI: For that patient for
3 that month.

4 CO-CHAIR ANDERSON: So, if you didn't
5 have all of the elements, that would fail?

6 DR. NISHIMI: The attestation.

7 CO-CHAIR ANDERSON: The attestation?

8 DR. NISHIMI: For that particular
9 patient in that particular month, yes. It may be
10 present for everyone else. Let's say there are
11 100 patients, and for one of your patients you
12 failed to document allergy. Then, that
13 particular patient would fail, but your other 99
14 patients would pass. So, for that patient-month,
15 your score would be 99, not 100.

16 DR. MCGONIGAL: And also, knowing that
17 if you try but you cannot find the information,
18 "unknown" is an acceptable response. You won't
19 fail if you put "unknown".

20 CO-CHAIR ANDERSON: And have you made
21 any accommodations for communication with non-
22 English-speaking patients or those that have

1 dementia? Or, certainly, it is easy to do
2 medication reconciliation with SNFs or wherever
3 the patient might reside, but what about those
4 other patients? Have you thought about that?

5 DR. NISHIMI: This measure is not just
6 risk-adjusted. I would think that for medication
7 review, the measure that focuses to a greater
8 degree on patient interaction, that will
9 potentially be a concern, sure.

10 CO-CHAIR ANDERSON: Any other comments
11 or questions?

12 (No response.)

13 Okay.

14 MR. LYZENGA: All right. Thanks to
15 everybody. That will be very useful feedback for
16 the Safety Committee.

17 Shall we move to the gaps discussion?

18 CO-CHAIR CROOKS: Yes. Okay.

19 Thank you very much and good luck with
20 that.

21 MR. LYZENGA: Yes, thanks, Lisa.

22 DR. MCGONIGAL: Thank you, everyone.

1 MR. LYZENGA: All right. So, with
2 respect to gaps, as I mentioned, we have a list
3 of the measures in the portfolio that I believe
4 we passed out to you. I don't know if anybody
5 has had a chance to look. But we would like to
6 take just a few moments to see if the Committee
7 has any particular thoughts on gap areas within
8 this topic area, you know, measures that you
9 think are lacking in this area or where you think
10 we are lacking measures in this particular area.

11 That could be on a particular topic
12 area. That could be types of measures. Maybe
13 you think we need more outcomes or more patient-
14 reported outcomes. Maybe you think we need
15 different levels of analysis, sort of any type of
16 gap that you think we are facing in terms of
17 measurement on the topic of renal care.

18 This is important for us because we do
19 try to feed this kind of information back to our
20 developer community. We are also trying to take
21 more of an active role as NQF in identifying gaps
22 and prioritizing gaps across the measurement

1 enterprise. So, it is very useful information for
2 us as well. So, we would welcome any feedback you
3 have on sort of the state of renal measurement
4 and where there are some important gaps.

5 MEMBER HARTWELL: Hi. This is Lori
6 Hartwell.

7 One of the measures that I have been
8 proposing for many years, although I think it
9 would be a little labor-intensive and I don't
10 know where you would get the data, but I think it
11 is the patient experience of treatment. And I
12 would like every single treatment.

13 In discussing with some of my peers,
14 they don't feel good after dialysis. If we could
15 get a handle on defining why they don't feel good
16 after dialysis. And there, I have passed this
17 measure out to many of the members on the
18 Committee. It is kind of a make-shift idea.

19 But I think that that would allow the
20 community to really understand why patients don't
21 adhere to treatment or they have problems.
22 Because once you don't feel good after treatment

1 and it repeats a few times, and you, then, start
2 to lose hope, and it is easy to not take your
3 medication, not go to work, not consider going to
4 work. It also has an impact on staff and staff
5 retention.

6 And I know this is a very big idea,
7 but I think it is critical to improving the
8 patient care on an individual basis because each
9 treatment is individual and it is how the patient
10 perceives it.

11 So, that is what I have to say.

12 It is so hard talking to a telephone,
13 just to let everybody know, like this.

14 CO-CHAIR CROOKS: We're listening,
15 Lori. I think that is a wonderful idea as an
16 example of a patient-centered outcome. It sounds
17 simple. It sounds important. I would love to
18 see somebody work with that.

19 Alan?

20 MEMBER KLIGER: Right. Well, we
21 mentioned this request last year as well, that
22 patient-reported outcomes and the PROMIS set of

1 areas for patient-reported outcomes are in
2 development in other areas.

3 Just my question for us is, where are
4 we in the development of our patient-reported
5 outcomes or utilizing the PROMIS set of areas for
6 measures? Are any under development? Are there
7 any developers that are doing that now? You
8 guys, are you guys aware of what is happening?

9 MR. LYZENGA: Not in this particular
10 area that I'm aware of. I should note that we
11 are certainly engaging in trying to advance
12 patient-reported outcome measure development in
13 general. And we have started an initiative that
14 we are calling our measure incubator. We are not
15 directly involved in measure development through
16 that activity, but are trying to sort of perform
17 a matchmaking service of sorts where we are
18 bringing together people with ideas about
19 measurement and those who have experience with
20 measure development funding and data, so that we
21 can really accelerate development of measures in
22 gap areas. And patient-reported outcomes is a

1 major one and that there has been significant
2 interest in. And we can carry your thoughts that
3 there is a need for this in this particular area
4 for patient-reported outcomes.

5 MEMBER KLIGER: Yeah, specifically, it
6 might be useful to speak to the people in PROMIS,
7 the Patient-Reported Outcomes Measurement
8 Information System folks, who have a really good
9 handle on the activities going on at various
10 places in the country on that. Perhaps
11 communication with that group might be really
12 helpful.

13 MS. SAMPSEL: And I can, so David
14 Cella, who is very involved in all the PROMIS
15 work, he is very active with NQF. So, typically,
16 what happens is, when he is working on something,
17 he says like, "Hey, let's talk about this one,
18 how we might be able to integrate." He hasn't
19 brought it up yet. So, certainly, it is something
20 we can follow up with him on.

21 MEMBER MADDUX: So, other than the
22 patient-reported outcomes, which I agree with,

1 there are three categories where I think it would
2 be useful to have some work done.

3 One is frailty and understanding how
4 we begin to measure what proportion of our
5 patients are really functionally quite frail.

6 The second is with the impact, the
7 tremendous impact of cardiovascular disease on
8 this population of patients, there aren't a lot
9 of bridging measures between what we consider
10 cardiology activity and nephrology activity. And
11 I think that would be useful.

12 And then, the third is the delivery
13 systems fail to achieve data exchange between
14 providers, particularly effectively, and creating
15 measures around the need and expectation for data
16 exchange, clinical data exchange that is useful,
17 not just techno stuff, would be a way to drive
18 that process, I think, and it would be an
19 interesting area of development.

20 CO-CHAIR ANDERSON: Andrew? Andrew,
21 is your card up, too? Do you have a comment?
22 But your card is up or your name.

1 Okay.

2 MEMBER EVANS: I was looking at
3 diabetes, both bridging that -- we seem to forget
4 managing that or monitoring that, and maybe some
5 harmonization with endocrinology because that is
6 our No. 1 reason for ESRD and increases the
7 larger interdialytic weight gains. And we should
8 be at least looking at that.

9 MEMBER KASKEL: So, last year we had
10 brought this up at the end, about looking at
11 preparedness for transition as a potential area
12 to develop. It is a problem that we face, as do
13 the internal medicine adult nephrologists. We
14 have a lot of young adults that transition, and
15 I'm not sure we have any standardized measures.
16 Everyone seems to have their own platform for
17 seeing if they are ready to do this leap from a
18 pediatric facility to an adult facility. I think
19 it is an area that is open for development. I am
20 not sure we do such a good job in preparing them.

21 MEMBER GREENSTEIN: So, I have to put
22 on my access hat. The area I think that there is

1 a tremendous gap is in terms of looking at
2 patients who are undergoing access procedures,
3 redo procedures. What do I mean by that? So, you
4 have patients who are getting dialyzed through a
5 fistula. They are going for repeat balloon
6 angioplasties. They are going for declottings.

7 And there is no handle on what is
8 truly the right way of handling this for
9 patients. Should they not go for the repeat
10 procedures? Is this a procedure that has failed?
11 They should go on to something else? Nobody has
12 a handle on that. So, I really think there is a
13 tremendous gap in outcomes for that.

14 MEMBER WAGNER: I think something that
15 perhaps should be looked at is the idea of
16 palliative dialysis and how to permit less-than-
17 three-times-a-week dialysis as long as it upholds
18 patient preferences and some quality-of-life
19 parameters without being abusive of reasonable
20 medical care.

21 MEMBER KLIGER: Yes, I was going to
22 mention that as well. But I have one other as

1 well.

2 When you come back to thinking about
3 patient preferences, it is also, I think,
4 important when we develop measures, to remember
5 that not all patients are the same. And things
6 that one patient finds valuable or important to
7 them will be different than what the next one
8 does.

9 And if we had ways of measuring
10 patient choices and priorities in their care, I
11 think that that would be really important and
12 distinct from patient-reported outcomes, really
13 an opportunity to allow each patient and their
14 family to decide what is really important to
15 them.

16 The 85-year-old woman who really only
17 wants to come to dialysis twice and for whom a
18 Kt/V is totally irrelevant, that priority for her
19 should be high in our measurement set of her
20 adequacy of treatment.

21 CO-CHAIR ANDERSON: And this is more
22 from the provider side. But one of the things

1 that is very frustrating, in particular, with
2 bloodstream infections is how it is measured and
3 calculated. The DFRs do it different than the CDC
4 and METC. And there has got to be a way to
5 harmonize, so everybody is measuring it the same
6 way.

7 And now, providers are also
8 responsible for, if a patient is admitted to the
9 hospital within 48 hours if they have a positive
10 blood culture, we are responsible for that
11 positive blood culture. But there is no way that
12 we would be able to get that information in a
13 timely manner.

14 There are also concerns because, if
15 you end with a bloodstream infection in one week
16 and it continues into the next, and you are still
17 giving the antibiotics, it is counted as two
18 separate events. So, somehow we have to come
19 together with how we are actually measuring and
20 reporting because everyone is doing it very
21 differently.

22 CO-CHAIR CROOKS: Lori, were you about

1 to say something?

2 MEMBER HARTWELL: Well, you know, I
3 don't know if this is -- one of the areas that
4 has been discussed in many of the different
5 groups recently is rehabilitation for people who
6 are working age. And I believe that the patient
7 experience of treatment drives quality of life,
8 can drive rehabilitation. But it also would be a
9 good indicator, especially with the changes in
10 healthcare and preexisting causes. I just wanted
11 to throw that one out there.

12 CO-CHAIR CROOKS: Thank you.

13 MEMBER WAGNER: An area that is
14 certainly problematic, but important for patient
15 outcomes is the first 30 days of dialysis.
16 Obviously, because of insurance issues, Medicare
17 coverage, that hasn't been a subject of much
18 attention, but, clearly, mortality and morbidity
19 is significant during this first 30 days.

20 MEMBER KLEINPETER: One additional
21 comment. We're having an influx of more
22 undocumented individuals, and those patients are

1 often getting care either through the emergency
2 department on a PRN basis -- so at least some
3 minimal standards in terms of the care of these
4 patients in nontraditional outpatient situations.

5 MEMBER WAGNER: Well, I mean, that just
6 reminded me I don't know if this is in our
7 mandate, but now that AKI patients will be
8 appearing in ESRD facilities again, this, I
9 guess, invites discussion regarding how those
10 metrics that we typically apply to dialysis care
11 should be applied to those populations.

12 CO-CHAIR CROOKS: I would like to sort
13 of underline the mention of palliative care. I
14 think it is really important to look at our
15 population both coming on dialysis and the
16 population of patients that probably are not
17 going to benefit from starting dialysis, and
18 whose responsibility is that? How that is
19 measured I don't know, but to have an appropriate
20 program in place to avoid dialyzing patients that
21 shouldn't start.

22 And then, conversely, patients who are

1 on dialysis who are ready to call it quits, how
2 effective are we at identifying those patients
3 and providing the service and the transition of
4 care so they can safely stop dialysis and go into
5 a hospice program?

6 MEMBER LATTIS: One more quick one, and
7 this might be either self-serving or self-
8 flagellating since I chair the Cost of Resource
9 Use Committee, and I don't know if it would go
10 here or there. But I think it would be valuable
11 to have a resource use on dialysis measure.

12 CO-CHAIR CROOKS: Does that exhaust
13 all of our possibilities for now? I know there
14 are many more possibilities.

15 MR. LYZENGA: Thank you all. That is
16 very helpful.

17 CO-CHAIR CROOKS: Thank you.

18 So, before we go to public comment, we
19 are going to have Alexandra, I guess, go over
20 next steps and Committee timeline.

21 MS. OGUNGBEMI: Yes. So, after our
22 lovely meeting this evening finishes, we will be

1 optionally having a post-meeting webinar? Okay,
2 we are not having a post-meeting webinar. So, I
3 will send a cancellation to you for that.

4 The NQF staff will draft the report,
5 and it will be posted for NQF member and public
6 comment from August 5th to September 6th. So,
7 that is a 30-day public comment period.

8 You all will have a conference call in
9 September, on the 23rd, to review and respond to
10 those comments. After that, the draft report
11 will be posted for NQF member vote from October
12 5th to 19th, and then, it will go to CSAC for
13 review and approval on December 9th or 10th. The
14 Board will, then, review it on December 8th, and
15 we will go through appeals December 12th through
16 January 10th.

17 MEMBER PAVLINAC: Sorry. So, no call
18 this Friday, is that correct?

19 MS. OGUNGBEMI: No call this Friday.
20 I will send a cancellation.

21 MEMBER PAVLINAC: Yay, I get vacation.
22 Thank you very much.

1 (Laughter.)

2 MR. LYZENGA: Operator, could you open
3 the lines for public comment?

4 OPERATOR: Yes, sir.

5 At this time, if you would like to
6 make a comment, please press *, then the No. 1.

7 (Pause.)

8 No, no public comments at this time.

9 MR. LYZENGA: Thank you.

10 Any public comments in the room?

11 (No response.)

12 No? No.

13 CO-CHAIR CROOKS: Okay. Well, that
14 concludes our business for today. I thank you
15 all for coming, for your efficient processing of
16 this difficult, sometimes challenging work. And
17 we will next be in touch in September, but watch
18 your emails.

19 All right. Okay. Thank you very much.

20 CO-CHAIR ANDERSON: Thanks, everyone.

21 (Whereupon, the above-entitled matter
22 went off the record at 3:59 p.m.)

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This is to certify that the foregoing transcript

In the matter of: Renal Measures Standing Committee

Before: NQF

Date: 06-28-16

Place: Washington, DC

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